

ECETOC

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Existing Chemicals Guidance for Completing the EEC Data Set

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SPECIAL REPORT

No. 1

EXISTING CHEMICALS

Guidance for Completing the EEC Data Set

Annex II of the EEC Commission
Proposal for a Council Regulation on
the Evaluation and Control of
Environmental Risk from Existing
Substances.
COM (90) 227 final – SYN276

Brussels, March 1991
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ECETOC Special Report

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Existing Chemicals: Guidance for completion of the EEC
Data Set for High Volume Existing Substances

1. Introduction

The release of certain chemical substances into the environment can result in exposure which may affect human health or endanger ecological systems because of toxic effects caused directly or after accumulation. Efforts have been made by international organisations and the chemical industry to identify these effects by toxicological or ecotoxicological programmes and by taking appropriate control measures.

In the past 20 years nearly all western industrialised countries with significant chemical production have adopted laws requiring a systematic evaluation of the harmful effects of chemical substances on man and the environment. Most of the existing legislation has concentrated on new substances, i.e. substances that are produced or placed on the market for the first time. Certain data must be submitted to the authorities before these substances may be produced or marketed. (EEC Council Directive, 1979).

Existing substances, i.e. those already in production or on the Community market before 18 September 1981, are now receiving more attention. The United States has introduced legislation which designates certain existing chemicals as priority chemicals for testing by means of its Toxic Substances Control Act (TSCA). A large number of chemical substances have been tested, particularly for carcinogenicity, within the National Toxicology Program (NTP). International Organisations such as the OECD and WHO have also developed programmes for the systematic evaluation of existing chemicals (OECD, 1986).

Because of the number of existing chemicals and the fact that many will present no problems, there is the need to identify those which are likely

to have the greatest hazard potential for further evaluation. To do this it is necessary to apply certain criteria in a stepwise fashion, firstly to select a starting list of chemicals on which further evaluation can be undertaken. The criteria for this first step can be based, for example, on production quantities or health hazard potential. Once a manageable list has been drawn up then a further priority setting process can be undertaken.

Based upon these considerations, the EEC Commission submitted a regulatory proposal to the EEC Council in September 1990 for the collection of information and risk evaluation of existing chemicals by a stepwise procedure. (Proposal for a Council Regulation on the Evaluation and Control of Environmental Risk from Existing Substances. COM (90) 227 final SYN 276. Official Journal of the European Communities C276 from 5.11.90 ISSN 0378 - 6986). A fundamental step of this process is the submission of available data by manufacturers and importers to the Commission in the form of a condensed, formalised data set (Annex II of this regulation).

More recently there has been an agreement between the EEC Commission and OECD to harmonise their data banks (including also the IRPTC data bank) to enable data to be exchanged between different electronic systems. For this purpose a new and extended data format has been devised as an EEC/OECD Draft Proposal on a Harmonised Electronic Data Input Set. While the situation is unclear, the data set as published in the Official Journal will remain the official version. However it is likely that the EEC/OECD draft form might replace the current document. The official EEC data set (Annex II of the Proposal) and the EEC/OECD draft form are shown in this report as Appendices 1 (yellow) and 2 (blue) respectively.

This report briefly describes the EEC Commission proposal and provides guidelines to companies on how to complete the forms for both the EEC data set and the EEC/OECD harmonised electronic data input set.

2. Proposal for a Council Regulation on the Evaluation and Control of Environmental Risks from Existing Substances (See Official Journal of the European Communities C276 of 5.11.1990 ISSN 0378-6986).

This proposal has been introduced in accordance with the provisions of Directive 67/548 EEC, and to ensure a harmonised approach in the Community. In drawing up the proposals the work already undertaken by OECD in this area was taken into account (OECD, 1986). The approval process in the European Community by the EEC-Council, Parliament and Economic and Social Committees is expected to be concluded by the end of 1991.

Although the proposal applies to about 100,000 substances listed in the EINECS inventory it is recognised that it would be impossible to collect the information to evaluate them all. Therefore, a systematic stepwise approach (represented by the scheme on the next page) is to be adopted whereby information is collected from industry on substances of production or import volume greater than 1000 tonnes/year known as High Volume Production Chemicals (given in Annex I of the EEC-Commission proposal). For these substances a data set must be submitted by manufactures or importers within 6 months of the regulation coming into force.

For those substances which are not listed in Annex I but are listed in the EINECS and are produced or imported in quantities exceeding 1,000 tonnes per year the data set must be submitted within 18 months (see articles 3 and 4 of the EEC - Commission proposal).

The data will be used by the Commission by means of a "Management Committee on the Systematic Evaluation of Existing Chemicals" (according to article 11 of the EEC-Commission proposal) to draw up priority lists of substances or groups of substances which will require further attention because of their possible effects on man and the environment or the absence of relevant information.

The data sets are similar to the "base set" for the notification of new substances under the Sixth Amendment. (EEC Council Directive, 1979).

EEC-scheme for identification of priority existing chemicals

E I N E C S

(about 100,000 substances)

|

v

Starting list of
approx. 2000 High Volume Production
Chemicals

|

v

Collection of available data on
biological effects and exposure

|

v

Identification of priority chemicals
by screening of data sets
(procedure still to be decided)

3. Guidance for completion of data sets for High Volume Existing Substances as defined in the EEC Commission Proposal.

3.1 General considerations

The EEC draft regulation requires that collection and presentation of data used for the screening phase should be done in a condensed format using a data set (see Appendix 1). The EEC/OECD draft proposal electronic data input set (see Appendix 2) is in a more extended format and requires completion in greater detail but this draft is still under review by the authorities at the time of publication of these guidelines.

Data to be included for both data sets will be derived from the published literature and from unpublished information from the manufacturers or importers. The data to be provided includes :

- production quantity
- exposure-orientated use-pattern information
- physico-chemical data allowing an assessment of the distribution of the chemical amongst environmental compartments
- environmental fate and pathways
- toxicological and ecotoxicological information

The use of the data set form of the EEC Commission proposal Annex II may cause difficulties because certain terms are not clearly defined and, in the case of toxicological and ecotoxicological data, presentational problems are caused by the format of the questionnaire.

Guidance on completing the EEC Commission proposal and EEC/OECD draft forms is based upon the following three assumptions:

- a) The biological data should be described in sufficient detail to evaluate the findings without the need to present the raw data.
- b) All available data should be taken into account for a specific endpoint. Data can only be ignored if it has been proved beyond doubt to be invalid. In cases of doubt the data should be included with a brief explanation of why there are reservations as to their validity.
- c) Where data are divergent, conflicting or difficult to interpret, an explanation justifying the results used needs to be given.

Accurate completion of these forms will be tedious but essential if sufficient information is to be made available to the "Management Committee". This committee will have the responsibility of assessing the information supplied by the manufacturer/importer and making recommendations to the Commission on priorities for further studies or "data gap filling" (Article 11 of the EEC Commission proposal). The Committee may be expected to balance the use-pattern of the chemical with the health and environmental data. So it is important that all available information is included, otherwise the committee may conclude that gaps in knowledge exist. Much effort can be expended in searching for data, especially to confirm it has never been produced. Manufacturers will need to judge when further investment in literature searching is worthwhile or cost-effective.

3.2 Specific Guidance for Completing the Forms

Guidance for completing the forms is given in the Appendices 1 and 2. In general, the guidance is confined to the toxicity and ecotoxicity sections. The following general guidance is applicable to both forms.

Section 1

Most of the requirements in Section 1 are self-explanatory.

General Information

It should be noted (re-Article 5 of the EEC Commission proposal), that if more than one Company is involved with the same compound, that each Company has to complete and submit the information specified in Section 1. With regard to the remaining sections it is possible for one manufacturer to take on the responsibility for completing and submitting the form on behalf of the other manufacturers, although this is not obligatory.

R-Phrases, S-Phrases

If, as a result of completing forms for a single compound, manufacturers note differences in their recommendations for R and S phrases where similar use patterns are envisaged, then it would be sensible to harmonise these divergencies before the submission of a data set.

Use Pattern

Data on use pattern have to be given by assigning substances to 4 groups according to the likely exposure resulting from their use and from the technology employed. It must be borne in mind that these categories, if not correctly understood may yield misleading information. In assigning chemicals, the following principles should be observed:

- a) A substance should be assigned to "Use in closed systems" group only if it remains within a reactor or is transferred from vessel to vessel through closed pipework (including transportation) and therefore accidental spillage is the only likely cause for human exposure or environmental contamination.

A typical example is phosgene which will be used only under those conditions.

Substances that are used in closed systems but might be released into the environment after use, sometimes in considerable quantities, or where significant discharges into the environment cannot be excluded during production or use, should be assigned to the 'Non dispersive use' or even 'Wide dispersive use' groups.

Typical examples in the latter case are CFC's used as cooling agents or hydraulic fluids.

- b) Use consisting of "inclusion into or onto matrices" means all processes where chemicals are incorporated into products or articles from which they would not be released into the environment. Examples are the inclusion of co-polymers in plastics, additives such as pigments or dyes in plastics or fibres and catalysts in coating materials.

Where the additive is likely to migrate in significant quantities out of the matrix into the environment or food, it will have to be assigned to the "non dispersive use" or "wide dispersive use" groups. A typical example in the first case is chemicals used for fibre preparations which are washed out after spinning or stretching and then discharged into waste water. An example in the second case is textile impregnating agents washed out after use.

- c) 'Non dispersive use' refers to chemicals which are used in such a way that only certain groups of workers, with a knowledge of the processes, come into contact with the chemicals. They are able to protect themselves and the environment against exposure through the use of personal or technical protective measures. Thus, exposure to these chemicals will be limited.

The chemicals may also be discharged into the environment as point sources. Quantities discharged should be limited due to protective measures such as waste water or exhaust air purification.

- d) The term 'wide dispersive use' should be used for a wide range of activities particularly where end-users come into contact with the products.

Classic examples are detergents, cosmetics, disinfectants, solvents in household paint etc.

Section 2. Physico - chemical data

The requirements in this Section are self-explanatory.

Section 3. Environmental Fate and Pathways

Test methods to determine whether chemicals are biodegradable are described in the Annex of Council directive 84/449/EEC. The methods are based on the OECD Guidelines. If possible use values derived from these methods. Chemicals that pass such tests are believed to be so readily biodegradable that they will be easily degraded in most environmental aerobic fresh waters or in sewage treatment plants (ECETOC, 1985. Technical Report No. 18 "Harmonisation of Ready Biodegradability Tests").

Other tests intended to find out whether chemicals are eliminated in waste water treatment plants (Zahn-Wellens-Test, Activated Sludge Simulation Test etc.) are described in Council Directive 87/302/EEC.

Section 4. Ecotoxicity

Test methods for the investigation of ecotoxicity are prescribed in Annex V of the Council directive 79/831/EEC of 18 September 1979, as laid down in Commission Directives 84/449/EEC of 24 April 1984 and 87/302/EEC of 18 November 1987. These test methods are mainly based upon OECD Test Guidelines. Test results should be reported as described in the guidelines.

Section 5. Toxicity

The test methods for the investigation of toxicity are prescribed in Annex V of Council directive 79/831/EEC, (1979) as laid down in Commission Directives 84/449/EEC (1984) and 87/302/EEC (1987). These methods are generally based upon OECD Test Guidelines. The test results should be reported in the terms shown on the data set forms.

Indicate whether carcinogenicity, mutagenicity and toxicity to reproduction has been shown in man or in animals or is only suspect (on the basis of animal or other evidence). The evidence should be summarised noting similarities and differences between results of individual tests and giving references to any evidence clarifying the reasons for such differences. Further guidance, if necessary, may be obtained from earlier ECETOC Publications (ECETOC, 1986, Technical Report No. 21, Guide to the Classification of Carcinogens, Mutagens and Teratogens under VI Amendment).

A particularly difficult situation arises when completing section 5.6 of the EEC Commission proposed form since the classifications for carcinogenicity, mutagenicity and toxicity to reproduction on the form do not correspond in all ways with classification guidance provided by the Commission. Detailed guidance on how to deal with this is given under 5.6 of the attached Appendix 1.

Section 6. Other data relevant to Risk Evaluation

All ECETOC comments to this section are given in Appendix 1.

4. Literature Sources

Adequate and reliable information is needed to complete the data set forms comprehensively and accurately. Apart from the manufacturers' own data, literature sources need to be consulted. There are numerous reference books and electronic data banks which can be searched to obtain this information on existing chemicals. Care must be taken to ensure that data so obtained refer to chemicals of the specification manufactured.

ECETOC (1989) Technical Report No 30(3) gives a literature overview on evaluations of the work done by several organisations with respect to evaluation of some 1800 existing chemicals.

Some on-line data banks contain abstracts which give some description of the results, and others only provide references. In both cases, it will be necessary to obtain the original publication in order to check that the data are valid and reliable.

The HOSTS offering the most important data bases on the properties of specific existing chemicals are:

CIS USER SUPPORT

Fraser Williams Scientific Systems
London House, London Rd South
Poynton, Cheshire
SK12 1YP
Tel. (044) 625876711

DIMDI

Deutsches Institut fuer Medizinische Dokumentation und Information
Postfach 420580
Weisshausstr. 27
D-5000 Koeln 41
Tel. 0221-4724-1

STN International

c/o Fachinformationszentrum Karlsruhe
Postfach 2465
D-7500 Karlsruhe 1
Tel. 07247-808-555

Data Star

Radio Schweiz AG, Data Star
Laupenstr. 18a
CH - 3008 Bern

The types of data bases and the kind of information supplied are shown in Table 1. In some cases they may not be able to supply the desired information. Other data bases which could be helpful are :

- ECDIN (HOST : DIMDI and Data Star)
Data base : toxicological properties
- CIN (HOST : STN)
Bibliographic data base : production of chemicals .
- ENVIROLINE (HOST : DIMDI)
Bibliographic data base : water pollution, chemical and biological contamination.
- POLLUTION ABSTRACTS (HOST: Data Star)
Bibliographic data base : air and water pollution, waste water, toxicology
- ULIDAT (HOST: STN and Data Star)
Bibliographic data base : environmental aspects.

Bibliography

- ECETOC (1989). Technical Report N°30(3). Existing Chemicals : Literature Reviews and Evaluations.
- EEC Council Directive (1979). Council Directive of the European Community 67/548/EEC. VI Amendment Council directive 79/831/EEC. Office of Official Publications of the EEC. 2, Rue Mercier, 2985 Luxembourg.
- OECD (1986). Existing Chemicals. Systematic Investigation Priority Setting and Chemicals Reviews. OECD rue André-Pascal 2, 75775 Paris Ceex 16 France.

Table 1. Data Bases and Type of Information Supplied

Name of data base Kind of data base	HOST	Physical and chemical properties	Toxicological data	Ecological data
AQUIRE	CIS			Acute, chronic, bioaccumulative and sublethal dat for freshwater and saltwater organisms
BEILSTEIN Facts data base	STN	Electrical and magnetic data, electrochemical behaviour, density, surface tension, solubility, boiling point, melting point, sublimation point and others		
CA Bibliographic data base	STN	Chemical data in abstracts	Toxicological data in abstracts	Ecological data in abstracts
ENVIROFATE Facts data base	CIS	log Pow, volatilization water solubility, vapour pressure, hydrolysis		Photolysis soil, air, water monitoring microbial degradation degradation in natural system, bioconcentration
HODOC Facts data base	STN	Boiling point, melting point, density, solubilities		

Table 1. Data Bases and Type of Information Supplied (continued)

Name of data base Kind of data base	HOST	Physical and chemical properties	Toxicological data	Ecological data
HSDB Facts data base	DIMDI		Toxicological data	
ISHOW Facts data base	CIS	Melting point, boiling point, vapour pressure, log part. coefficient, solubility in water		
OHM/TADS Facts data base	CIS	Physical and chemical data plus interpretive comments and advice in emergency situation	Toxicological data	Biological data
PHYTOTOX Facts data base	CIS			Effects of application to a particular terrestrial vascular plant
RTECS Facts data base	DIMDI CIS		Toxicity data and regulations for chemicals by US law	
SOLUB Facts data base	CIS	Aqueous solubility data for organic compounds, excluding salts		
TOXALL addition of toxicolo- gical parts of different data bases (e.g. CA, MEDLINE, BIOSIS)	DIMDI		Carcinogenity, mutagenity, teratogenity, toxicology	

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APPENDIX 1

Annex II

**Data Set of the EEC Proposal for a Council Regulation
on the Evaluation and the Control of the Environmental
Risk from Existing Substances. COM (90) 227 final - SYN276**

ANNEX II

INFORMATION REQUIRED FOR THE DATA SET REFERRED TO IN
ARTICLES 3 AND 4 (1)

In submitting the information referred to in Articles 3 and 4 (1), the manufacturer and importers shall use a special form for optical reading or a special computerized programme on diskette. A facsimile of the data set is given in this Annex. The data set will be made available by the Commission through the Press and Information Offices in the Community (see Annex IV).

The manufacturers and the importers shall apply the rules set out below when filling in the data set for existing substances.

1.1. *Name of the substance*

Use the IUPAC name.

1.2. *Einecs No*

Number given to the substance in the European inventory of existing commercial chemical substances.

1.3. *CAS No*

Number given by the Chemical Abstracts Service.

1.4. *Synonyms*

Indicate the most common synonyms.

1.5. *Purity*

Indicate the purity in percentage terms.

1.6. *Molecular formula*

Indicate the molecular formula.

1.7. *Known impurities*

Indicate, if available, name, CAS No, Einecs No and quantity in percentage terms of the impurities which have dangerous properties.

1.8. *Structural formula*

Indicate the structural formula.

1.9. *Type of substance*

Indicate the type of substances.

Page 1	FOR COMMISSION USE
<input type="checkbox"/>	<input type="checkbox"/>

DATA SET FOR EXISTING SUBSTANCES

1.1. *Name of the substance*1.2. *Einecs No*1.3. *CAS No*1.4. *Synonyms*1.5. *Purity*1.6. *Molecular formula*1.7. *Known impurities*☐ %

Einecs No

CAS No

☐ %

Einecs No

CAS No

1.8. *Structural formula*1.9. *Type of substance*

Inorganic

01

Organic

02

Organometallics

03

Element

04

Petroleum product

05

FOR COMMISSION USE

Postmark

(1) Chemical name of the impurity

1.4. *Synonyms:*

Common synonyms e.g. ACETONE, ISOPHORONE etc. Not trade names.

1.5. *Purity:*

Purity according to technical specification.

Page 2 FOR COMMISSION USE

1.10. *Name of the producer*

ADDRESS:

No

Street

Town Postal code Cedex

Country Code Telephone Ext:

Telex Telefax

[illegible]

1.11 *Name of the importer*

--

ADDRESS:

No.

Street

Town Postal code Cedex

Country Code Telephone Ext.

Telex Telefax

FOR COMMISSION USE

1.12. Quantity produced or imported greater than 1 000 tonnes per year

Indicate the quantity range of the substance produced within the Community, or imported into the Community, at least once in the past three years, if greater than 1 000 tonnes per year.

1.13. Indicate if the substance has been produced during the past 12 months.

1.14. Indicate if the substance has been imported during the past 12 months.

1.15. Classification by EEC Directive

If the substance is in Annex I to Directive 67/548/EEC then it is classified accordingly

— Provisional classification by manufacturers or importers

If the substance is not in Annex I to Directive 67/548/EEC June 1967, but has dangerous properties, then the substance should be provisionally classified by the manufacturer or importers.

— No classification (no dangerous properties)

If the substance has no dangerous properties within the meaning of Directive 67/548/EEC, then no classification is required.

— No classification (no data available)

The dangerous properties of the substance are unknown.

1.16. Symbols

Use the symbols specified in Annex II to Directive 67/548/EEC.

1.17. Risk phrases

Use the R-phrases specified in Annex III to Directive 67/548/EEC.

1.18. Safety phrases

Use the S-phrases specified in Annex IV to Directive 67/548/EEC.

Page 3		FOR COMMISSION USE									
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

1.12. Quantity produced and imported, greater than 1 000 tonnes per year

Quantity range (tonnes per year)	Produced	Imported
1 000 to 5 000	<input type="checkbox"/>	<input type="checkbox"/>
5 000 to 10 000	<input type="checkbox"/>	<input type="checkbox"/>
10 000 to 50 000	<input type="checkbox"/>	<input type="checkbox"/>
50 000 to 100 000	<input type="checkbox"/>	<input type="checkbox"/>
100 000 to 500 000	<input type="checkbox"/>	<input type="checkbox"/>
500 000 to 1 000 000	<input type="checkbox"/>	<input type="checkbox"/>
more than 1 000 000	<input type="checkbox"/>	<input type="checkbox"/>

1.13. Indicate if the substance has been produced during the past 12 months

1.14. Indicate if the substance has been imported during the past 12 months

1.15. Is the substance classified by

EEC Directive 67/548/EEC ☐Provisional classification: ☐No classification:
No dangerous properties: ☐No classification:
No data available: ☐

1.17. R-phrases

R1 <input type="checkbox"/>	R14 <input type="checkbox"/>	R27 <input type="checkbox"/>	R40 <input type="checkbox"/>
R2 <input type="checkbox"/>	R15 <input type="checkbox"/>	R28 <input type="checkbox"/>	R41 <input type="checkbox"/>
R3 <input type="checkbox"/>	R16 <input type="checkbox"/>	R29 <input type="checkbox"/>	R42 <input type="checkbox"/>
R4 <input type="checkbox"/>	R17 <input type="checkbox"/>	R30 <input type="checkbox"/>	R43 <input type="checkbox"/>
R5 <input type="checkbox"/>	R18 <input type="checkbox"/>	R31 <input type="checkbox"/>	R44 <input type="checkbox"/>
R6 <input type="checkbox"/>	R19 <input type="checkbox"/>	R32 <input type="checkbox"/>	R45 <input type="checkbox"/>
R7 <input type="checkbox"/>	R20 <input type="checkbox"/>	R33 <input type="checkbox"/>	R46 <input type="checkbox"/>
R8 <input type="checkbox"/>	R21 <input type="checkbox"/>	R34 <input type="checkbox"/>	R47 <input type="checkbox"/>
R9 <input type="checkbox"/>	R22 <input type="checkbox"/>	R35 <input type="checkbox"/>	R48 <input type="checkbox"/>
R10 <input type="checkbox"/>	R23 <input type="checkbox"/>	R36 <input type="checkbox"/>	
R11 <input type="checkbox"/>	R24 <input type="checkbox"/>	R37 <input type="checkbox"/>	
R12 <input type="checkbox"/>	R25 <input type="checkbox"/>	R38 <input type="checkbox"/>	
R13 <input type="checkbox"/>	R26 <input type="checkbox"/>	R39 <input type="checkbox"/>	

Yes No

☐ ☐☐ ☐

1.16. Symbols

E	O	F ₊	F	T ₊	T	C	X _n	X _i
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

1.18. S-phrases

S1 <input type="checkbox"/>	S14 <input type="checkbox"/>	S27 <input type="checkbox"/>	S40 <input type="checkbox"/>	SS3 <input type="checkbox"/>
S2 <input type="checkbox"/>	S15 <input type="checkbox"/>	S28 <input type="checkbox"/>	S41 <input type="checkbox"/>	
S3 <input type="checkbox"/>	S16 <input type="checkbox"/>	S29 <input type="checkbox"/>	S42 <input type="checkbox"/>	
S4 <input type="checkbox"/>	S17 <input type="checkbox"/>	S30 <input type="checkbox"/>	S43 <input type="checkbox"/>	
S5 <input type="checkbox"/>	S18 <input type="checkbox"/>	S31 <input type="checkbox"/>	S44 <input type="checkbox"/>	
S6 <input type="checkbox"/>	S19 <input type="checkbox"/>	S32 <input type="checkbox"/>	S45 <input type="checkbox"/>	
S7 <input type="checkbox"/>	S20 <input type="checkbox"/>	S33 <input type="checkbox"/>	S46 <input type="checkbox"/>	
S8 <input type="checkbox"/>	S21 <input type="checkbox"/>	S34 <input type="checkbox"/>	S47 <input type="checkbox"/>	
S9 <input type="checkbox"/>	S22 <input type="checkbox"/>	S35 <input type="checkbox"/>	S48 <input type="checkbox"/>	
S10 <input type="checkbox"/>	S23 <input type="checkbox"/>	S36 <input type="checkbox"/>	S49 <input type="checkbox"/>	
S11 <input type="checkbox"/>	S24 <input type="checkbox"/>	S37 <input type="checkbox"/>	S50 <input type="checkbox"/>	
S12 <input type="checkbox"/>	S25 <input type="checkbox"/>	S38 <input type="checkbox"/>	S51 <input type="checkbox"/>	
S13 <input type="checkbox"/>	S26 <input type="checkbox"/>	S39 <input type="checkbox"/>	S52 <input type="checkbox"/>	

1.12. Quantity produced and imported, greater than 1000 tonnes per year.

Indicate if the greatest amount produced is exported outside the EEC.

1.13. Indicate if the substance has been produced during the past 12 months:

1.14. Indicate if the substance has been imported during the past 12 months:

Deadline: the end of the last year.

1.17. R-phrases:

1.18. S-phrases:

See comment on page 7 of this report.

1.19 Use patterns in percentage terms

Indicate the different uses of the substance and give the relevant percentage for each use. This information must be given only if available.

— Use in closed systems

Exposure is very limited. Emissions into the environment are normally limited to losses during production and disposal of production residues or losses due to accidents, e.g. refineries, corrosion inhibitors in a steam or hot water heating system.

— Use resulting in inclusion into or onto a matrix

Substances are fixed into or onto matrices from which, under normal conditions they cannot be removed. Emissions and exposure may occur during the application process and to a limited extent after disposal, e.g. plasticizers in plastics, anti-oxidizing agents in rubber, catalysts in wax-pellets.

— Non-dispersive use

Substances are emitted during application and exposure may take place but only where there are trained personnel and under controlled conditions, e.g. in a special paint spraying area or dry cleaners.

— Wide dispersive use

Substances will be released into the environment to a large extent during use. There is also significant exposure to untrained consumers, e.g. fertilizers and pesticides; painting walls and doors and spraying.

Page 4		FOR COMMISSION USE									
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

1.19. Use patterns in percentage terms

	Use in a closed system	Use resulting in inclusion into or onto matrix	Non-dispersive use	Wide-dispersive use
Adhesive materials	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Building materials and additives	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Catalysts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ceramic materials	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cleaning, washing agents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Conserving agents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cooling agents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Corrosion inhibitors	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cosmetics	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Deforming agents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
De-icing agents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Disinfectants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dispersion agents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dyeing auxiliaries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dyestuff, pigments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Feed additives	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fertilizer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Filler	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Flame retardants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hydraulic fluids	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Laboratory chemicals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Leather impregnating agents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lubricants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Oxidizing agents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

1.19 Use Patterns in percentage terms.

See general comments on page 7 and 8 of this report.

1.19. Use patterns in percentage terms

Indicate the different uses of the substance and give the relevant percentage for each use. This information must be given only if available.

— Use in closed systems

Exposure is very limited. Emissions into the environment are normally limited to losses during production and disposal of production residues or losses due to accidents, e.g. refineries, corrosion inhibitors in a steam or hot water heating system.

— Use resulting in inclusion into or onto a matrix

Substances are fixed into or onto matrices from which, under normal conditions they cannot be removed. Emissions and exposure may occur during the application process and to a limited extent after disposal, e.g. plasticizers in plastics, anti-oxidizing agents in rubber, catalysts in wax-pellets.

— Non-dispersive use

Substances are emitted during application and exposure may take place but only where there are untrained personnel and under controlled conditions, e.g. in a special paint spraying area or dry cleaners.

— Wide dispersive use

Substances will be released into the environment to a large extent during use. There is also significant exposure to untrained consumers, e.g. fertilizers and pesticides; painting walls and doors and spraying.

1.20. Indicate the manufacturer or importer who is responsible for having filled in and returned the complete data set.

1.21. Indicate if you are the manufacturer or importer responsible for having filled in and returned the complete data set.

Page 5		FOR COMMISSION USE									
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Use in a closed system	Use resulting in inclusion into or onto matrix	Non-dispersive use	Wide-dispersive use
Paper, paper-additives	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pesticides	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pharmaceuticals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Photo-chemicals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Plastic additives and auxiliaries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Solvents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Stabilizer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Tanning agents and auxiliaries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Textile auxiliaries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Thickening agents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Vulcanizers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other use	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

1.20. Has the complete data set already been submitted by another manufacturer or importer?
(a) If yes, then indicate the manufacturer or importer who is responsible for having filled in and returned the completed data set

Yes ☐ No ☐

Name of the responsible manufacturer or importer

ADDRESS:

No ☐ Street

Town Postal code Cedex

Country Code Telephone Ext.

Telex Telefax

(b) If no, continue to fill in the data set.

FOR COMMISSION USE									
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

1.21. Specify if you are acting on behalf of other concerned manufacturers or importers

Yes ☐ No ☐

1.19 Use Patterns in percentage terms.

See general comments on page 7 and 8 of this report.

Page 6	FOR COMMISSION USE									
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. Physico-chemical data

Use, if possible, the value according to the test methods specified in Annex V to Directive 79/831/EEC, as laid down in Commission Directive 84/449/EEC of 25 April 1984⁽¹⁾. These test methods are usually based on the OECD test guidelines.

2.1. Boiling point/boiling range

2.2. Melting point/melting range

2.3. Vapour pressure

2.4. Water solubility

2.5. Fat solubility

2.6. Partition coefficient

2.7. Flash point

2.8. Auto-flammability

2.9. Flammability

2.10. Explosive properties

3. Environmental fate and pathways

Use, if possible, the value according to the test methods prescribed in Annex V to Directive 79/831/EEC, as laid down in Directive 84/449/EEC. These test methods are usually based on the OECD test guidelines.

3.1. Bioaccumulation

Indicate if possible the bioconcentration factor (BCF).

3.2. Biodegradation

Use if possible the values of one or more biodegradation tests (modified OECD test, modified AFNOR test T90/302, modified STURM test, Closed bottle test, modified MITI test and/or other tests).

3.3. Cod and Bod₅

In those cases where only COD (chemical oxygen demand) and BOD₅ (biochemical oxygen demand after five days) are available, use if possible the ratio BOD₅/COD.

⁽¹⁾ OJ No L 231, 19.9.1984, p. 1.

2. PHYSICO-CHEMICAL DATA

2.1. Boiling point	<input type="text"/>	°C at	<input type="text"/>	hPa	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Boiling range	from	<input type="text"/>	to	<input type="text"/>	°C at	<input type="text"/>	hPa	<input type="text"/>	<input type="text"/>
2.2. Melting point	<input type="text"/>	°C							
Melting range	from	<input type="text"/>	to	<input type="text"/>	°C				
2.3. Vapour pressure	<input type="text"/>	hPa at	<input type="text"/>	°C					
2.4. Water solubility	<input type="text"/>	mg/l at	<input type="text"/>	°C					
2.5. Fat solubility	<input type="text"/>	mg/kg at	<input type="text"/>	°C					
2.6. Partition coefficient	log P _{ow}	<input type="text"/>	cal	<input type="text"/>	meas.	<input type="text"/>			
2.7. Flash point	<input type="text"/>	°C							
2.8. Auto-flammability	<input type="text"/>	°C							
2.9. Flammability	<input type="text"/>	°C							
2.10. Explosive properties			Yes	No					

3. ENVIRONMENTAL FATE AND PATHWAYS

3.1. Bioaccumulation									
Bioconcentration factor	(BCF)	<input type="text"/>							
3.2. Biodegradation level after 28 days in percentage terms									
28 days									
Modified OECD test		<input type="text"/>	%						
Modified AFNOR test (T90/302)		<input type="text"/>	%						
Modified Sturm test		<input type="text"/>	%						
Closed bottle test		<input type="text"/>	%						
Modified MITI test		<input type="text"/>	%						
Other test		<input type="text"/>	%						
3.3. In those cases where the COD and BOD ₅ values are available, use the BOD ₅ /COD ratio									
BOD ₅		<input type="text"/>							
COD		<input type="text"/>							
Ratio BOD ₅ /COD		<input type="text"/>							

⁽¹⁾ Data not available

3. Environmental Fate and Pathways

For test methods which are applied to determine whether chemicals are biodegradable see Annex of Council Directive 84/449/EEC. The methods are based on the OECD Test Guidelines for testing of chemicals. Please use, if possible, values according to these test methods. Chemicals that pass such tests are considered to be so readily biodegradable that they will be easily degraded in most environmental aerobic fresh waters or in sewage treatment plants (ECETOC, 1985, T.R. No; 18 "Harmonisation of Ready Biodegradability Tests"). See also "Explanatory remarks" below.

Other test intended to find out whether chemicals are eliminated in waste water treatment plants (Zahn-Wellens-Test. Activated Sludge Simulation Test etc.) are laid down in Council Directive 88/302/EEC. (for more details see below "Explanatory remarks").

3.1 Bioaccumulation

Indicate the bioconcentration factor BCF (factor describing the relation between the concentration of a chemical in water and its concentration in the organism after equilibration). Comments on a test e.g. test organism, test conditions, concentration determinations, duration of exposition, accumulation and depuration kinetics, metabolism should be given on an additional page. Likewise, calculated values, together with correlation formulas and experimental references, and observations in natural habitats/biotops which indicate possible bioaccumulation should be presented on an additional page together with the available references in support.

3.2 Biodegradation

Indicate whether evidence exists showing that the substance is biodegradable. Use if possible the value of more than one biodegradation test. Any test which is not standardised by EEC or OECD guidelines please notice under 6.1. Provide all available references in support.

3.3 COD and BOD₅

If only COD (Chemical Oxygen Demand) and BOD₅-values (Biochemical Oxygen Demand after 5 days) are available, give percentage of BOD₅/COD ratio and provide the available reference(s) in support. Chemicals with BOD values in the range of 20% COD or less need to be investigated further by biodegradation tests.

Explanatory remarks

In biodegradation tests a substance under investigation (the substrate) is contained in a fixed amount of test medium and determined analytically as a function of time (normally 28 days). Biodegradation is due to microorganisms inoculated from various sources (ECETOC 1983, T.R. No. 8; "Biodegradation of Ready Biodegradability Tests: An Assessment of the Present Status").

The Modified OECD Screening Test and the Modified AFNOR Test are a kind of DOC Die Away Tests: Biodegradation of the test substance is measured by following a decrease of initially added 20 or 40 mg/l dissolved organic carbon (DOC). Regularly 11 test volume is incubated at room temperature in an 2l Erlenmeyer flask and aerated by shaking.

In the Modified Sturmtest evolution of CO₂ during the mineralisation of the test compound is quantitated within absorption vessels through which the outgoing gas flushes.

The respirometric methods (e.g. Closed Bottle Test, Modified MITI Test and the BOD₅ Test) substantiate the oxidation process of the biodegraded compound by recording the oxygen consumption during the test period. Biodegradation is expressed as BOD₅/COD ratio (where BOD is the biochemical and COD the chemical oxygen demand).

4. Ecotoxicity

Use, if possible, the value according to the test methods prescribed in Annex V to Directive 79/831/EEC, as laid down in Directives 84/449/EEC, and in Commission Directive 87/302/EEC of 18 November 1987 (*). These test methods are usually based on the OECD test guidelines.

4.1. Acute toxicity to fish

4.2. Acute toxicity to daphnia

4.3. Acute toxicity to algae

5. Toxicity

Use, if possible, the value according to the test methods prescribed in Annex V to Directive 79/831/EEC, as laid down in Directives 84/449/EEC and 87/302/EEC. These test methods are usually based on the OECD guidelines.

5.1. Acute toxicity

Use if possible the LD₅₀ and/or LC₅₀ values for rats or the species used.

5.2. Corrosive properties

5.3. Irritant properties

5.4. Sensitization

5.5. Sub-acute toxicity
(A short summary of the results must be given.)

LOEL = Low observed effect level
NOEL = No observed effect level

Page 7	FOR COMMISSION USE
<input type="checkbox"/>	<input type="checkbox"/>

4. ECOTOXICITY

4.1. Acute toxicity to fish

Duration (h)

Species

DNA(*)

Reference Nos

☐ LC₅₀☐ mg/litre☐ EC₅₀☐ mg/litre☐ EC₅₀☐ mg/litre

5. TOXICITY

5.1. Acute toxicity

LD₅₀ oral☐ mg/kgLD₅₀ dermal☐ mg/kgLC₅₀ inhalative☐ mg/litre

Yes

No

5.2. Corrosive properties

(a) Causes severe burns

(b) Causes burns

5.3. Irritant properties

(a) Irritating to skin

(b) Irritating to eyes

5.4. Sensitization

5.5. Sub-acute toxicity

Duration

28 days

x days

Species

LOEL oral

☐ mg/kg/day

LOEL skin

☐ mg/kg/day

LOEL inhalation

☐ mg/litre/day

Duration

28 days

x days

Species

NOEL oral

☐ mg/kg/day

NOEL skin

☐ mg/kg/day

NOEL inhalation

☐ mg/litre/day

(*) Data not available

4. ECOTOXICITY

Common test methods for investigation of ecological data are prescribed in Annex V of Council Directive 79/831/EEC of 18 September 1979, as laid down in Commission Directives 84/449/EEC of 24 April 1984 and 87/302/EEC of 18 November 1987. These test methods are usually based on OECD Test Guidelines. Please note test results according to these guidelines. Results from test methods not standardized by normed guidelines should be quoted under section 6.4.

4.1 Acute toxicity to fish

Indicate whether toxic effects on fish were found. Give the results as LC50 (concentration with 50% lethal effects) together with the duration of the test (in hours). Where a range of values is available, the minimum and maximum figures should be quoted. Comments on a test e.g. use of dispersants/solvents, effect of pH on toxicity, closed or open test systems, evaluation of the dose-response-curve, LC0, LC100, NOEC, narcotic effects should be given on additional page. Provide all available references in support.

4.2 Acute toxicity to daphnia

Indicate whether toxic effects on daphnia were found. Give the results as EC50 (concentration with 50% effects) together with the duration of the test (in hours). Where a range of values is available, the minimum and maximum figures should be quoted.

Comments on a test e.g. use of dispersants/solvents, effect of pH on toxicity, closed or open test system, evaluation of the dose-response-curve, EC0, EC100, NOEC, narcotic effects should be given on additional page. Provide all available references in support.

4.3 Acute toxicity to algae

Indicate whether toxic effects on algae were found. Give the results as EC50 (concentration with 50% effects) together with the duration of the test (in hours). Where a range of values is available, the minimum and maximum figures should be quoted. Comments on a test e.g. use of dispersants/solvents, effect of pH on toxicity, closed or open test system, evaluation of the dose-response curve, EC10, EC100, NOEC, bleaching of algae, effects on photosynthesis, substance incorporation into algal biomass should be given on additional page. Provide all available references in support.

4. **Ecotoxicity**

Use, if possible, the value according to the test methods prescribed in Annex V to Directive 79/831/EEC, as laid down in Directives 84/449/EEC, and in Commission Directive 87/302/EEC of 18 November 1987 ⁽¹⁾. These test methods are usually based on the OECD test guidelines.

4.1. **Acute toxicity to fish**4.2. **Acute toxicity to daphnia**4.3. **Acute toxicity to algae**5. **Toxicity**

Use, if possible, the value according to the test methods prescribed in Annex V to Directive 79/831/EEC, as laid down in Directives 84/449/EEC and 87/302/EEC. These test methods are usually based on the OECD test guidelines.

5.1. **Acute toxicity**

Use if possible the LD₅₀ and/or LC₅₀ values for rats or the species used.

5.2. **Corrosive properties**5.3. **Irritant properties**5.4. **Sensitisation**5.5. **Sub-acute toxicity**
(A short summary of the results must be given.)

LOEL = Low observed effect level
NOEL = No observed effect level

Page 7		FOR COMMISSION USE	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. **ECOTOXICITY**

Duration (h)

Species

DNA⁽¹⁾ Reference Nos4.1. **Acute toxicity to fish**LD₅₀

mg/litre

4.2. **Acute toxicity to daphnia**EC₅₀

mg/litre

4.3. **Acute toxicity to algae**EC₅₀

mg/litre

5. **TOXICITY**5.1. **Acute toxicity**

Species

LD₅₀ oral

mg/kg

LD₅₀ dermal

mg/kg

LC₅₀ inhalative

mg/litre

5.2. **Corrosive properties**

(a) Causes severe burns

(b) Causes burns

5.3. **Irritant properties**

(a) Irritating to skin

(b) Irritating to eyes

5.4. **Sensitization**5.5. **Sub-acute toxicity**

Duration

28 days

x days

Species

LOEL oral

mg/kg/day

LOEL skin

mg/kg/day

LOEL inhalation

mg/litre/day

Duration

28 days

x days

Species

NOEL oral

mg/kg/day

NOEL skin

mg/kg/day

NOEL inhalation

mg/litre/day

⁽¹⁾ Data not available

5.1 **Acute Toxicity**

The figures for the LD₅₀ and LC₅₀ should be inserted along with the species and the vehicle in which the estimates were made and references which substantiate the figures. Where a range of values is available, the minimum and maximum figures should be quoted with the species tested; give references to support all figures falling within the range.

5.2 **Corrosive properties**

Indicate whether evidence exists showing that the substance has corrosive properties or is free from corrosive properties. Indicate species tested and give references in support. Where data demonstrate adequately that it will cause burns or severe burns this should be indicated. Where data are equivocal this should be indicated by writing 'equivocal' and provide all available references in support. (ECETOC 1990 Monograph N°15 Skin Irritation).

5.3 **Irritant properties**

Indicate whether data are available to show that the substance is an irritant or free from irritant properties. Where irritancy has been demonstrated in eyes or on skin this should be indicated and the species tested as well. Where data are equivocal this should be indicated by writing 'equivocal' across the boxes and provide all available references in support. (ECETOC 1988 Monograph N°11 Eye Irritation, ECETOC 1990 Monograph N°15 Skin Irritation).

5.4 **Sensitisation**

Indicate whether data are available to show that the substance is capable of inducing allergic sensitisation. Indicate species tested. Where data are equivocal (e.g. substance causes sensitisation in some animal tests but not others or induces sensitivity in animals but no evidence of sensitisation in exposed human subjects). Provide all available references in support. (ECETOC 1990 Monograph N°14 'Skin Sensitisation Testing').

5.5 **Subacute toxicity**

Indicate the lowest exposure level which produces adverse effects (LOEL), the period of such exposure and the species examined by oral, skin or inhalation exposure. Where a range of values is available the minimum and maximum figures should be given with the species tested; give references to support all figures falling within this range.

Indicate the no observed effect level of exposure (NOEL) in a similar manner. In addition, summarise the findings of all subacute studies (studies in which animals have been exposed constantly or repeated to a substance over periods from a few days to 1/10 of their life span). This summary should, if possible,

- list principal adverse effects seen in test animals together with the exposure route(s), period(s), species and lowest exposure level at which each effect occurred.
- list the lowest no-observed level of exposure for each type of adverse effect.
- define on the most sensitive species; comment on the relevance of the findings in the most sensitive species and other species tested (if markedly different from the most sensitive) to man.
- comment on the possible mechanism of toxic action (if indicated by the animal tests) and its relevance to man.

Give references to support statements made in this summary.

5.6. *Carcinogenicity, mutagenicity, toxicity to reproduction*
(A short summary of the results must be given)

(i) Carcinogenicity

Category 1

Substances known to be carcinogenic to man. There is sufficient evidence to establish a causal association between human exposure to a substance and the development of cancer.

Category 2

Substances which should be regarded as if they are carcinogenic to man. There is sufficient evidence to provide a strong presumption that human exposure to a substance may result in the development of cancer, generally on the basis of:

- appropriate long-term animal studies,
- other relevant information.

Category 3

Substances which cause concern for man owing to possible carcinogenic effects but in respect of which the available information is not adequate for making a satisfactory assessment. There is some evidence from appropriate animal studies, but this is insufficient to place the substance in category 2.

(ii) Mutagenicity

Category 1

Substances known to be mutagenic to man. There is sufficient evidence to establish a causal association between human exposure to a substance and heritable genetic damage.

Category 2

Substances which should be regarded as if they are mutagenic to man. There is sufficient evidence to provide a strong presumption that human exposure to the substance may result in the development of heritable genetic damage, generally on the basis of:

- appropriate animal studies,
- other relevant information.

Category 3

Substances which cause concern for man owing to possible mutagenic effects but in respect of which the available information does not satisfactorily demonstrate heritable genetic damage. There is evidence from appropriate mutagenicity studies, but this is insufficient to place the substance in category 2.

(iii) Toxicity to reproduction

Substances causing impairment of fertility

Category 1

Substances known to cause impairment of fertility in humans (male and/or female). There is sufficient evidence to establish a causal association between human exposure to a substance and subsequent impairment of fertility.

Category 2

Substances which should be regarded as if they cause impairment of fertility to humans (male and/or female). There is sufficient evidence to provide a strong presumption that human exposure to the substance may result in effects on male or female fertility, on the basis of strong evidence from animal studies.

Summary of 5.5

Reference Nos

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

5.6. *Carcinogenicity, mutagenicity, toxicity to reproduction*

	Category (1)		Category (2)		Category (3)		DNA(*) Reference Nos			
	Yes	No	Yes	No	Yes	No				
Carcinogenicity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mutagenicity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Toxicity to reproduction	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- (1) Effects on man.
(2) Effects on animals.
(3) Suspected effects.
(*) Data not available.

5.6 Carcinogenicity, mutagenicity, toxicity to reproduction

Additionally the description given by the commission under 5.6, ECETOC (1986) Technical Report No. 21 'Guide to the Classification of Carcinogens, Mutagens and Teratogens under VI Amendment' contains detailed guidance on how to assess the data which is available and assign the chemical to the appropriate category. The process will require consultation with relevant experts in each area. This will ensure that the data supplied to the Commission will be consistent and manufacturers will be seen to have a common understanding of the assessment of carcinogens and mutagens.

iii) Toxicity to reproduction

When the reporting form is checked, it will be seen that only the one property of Toxicity to Reproduction with 3 categories is available for completion and the two components of Toxicity to Reproduction which are described in the preamble are not identified separately.

It is recommended therefore that when completing this part of the reporting form, reference is again made to ECETOC Technical Report No. 21 which refers to and provides guidance on, the three categories of teratogens (or 'developmental toxins') and the reporting form is suitably annotated if such teratogenic properties are present.

If impairment of fertility is suspected (with or without developmental toxicity) then the ECETOC Technical Report No. 21 does not address this. Accordingly, the manufacturer must assess the available data and with expert input decide which of the 2 categories (as described in the preamble to Annex II) is appropriate and, presumably therefore, strike out the 3rd box on the reporting form itself.

ECETOC Technical Report No. 21 has also been published as: Criteria for Identifying and Classifying Carcinogens, Mutagens and Teratogens. Regulatory Toxicity and Pharmacology (1987) 7 1-20.

5.6. cont. *Carcinogenicity, mutagenicity, toxicity to reproduction*
(A short summary of the results must be given)

Substances causing development toxicity

Developmental toxicity includes embryo-fetal toxicity, embryo-fetal death, structural and/or functional defects, peri-/post natal toxicity.

Category 1

Substances known to cause developmental toxicity to man. There is sufficient evidence to establish a causal association between human exposure to a substance and subsequent non-hereditary birth defects in offspring.

Category 2

Substances which should be regarded as if they cause developmental toxicity to man. There is sufficient evidence to provide a strong presumption that human exposure to the substance may result in non-hereditary birth in offspring, generally on the basis of appropriate animal studies.

Category 3

Substances which cause concern for man owing to possible developmental toxicity but in respect of which the available information is not adequate for making a satisfactory assessment. There is some evidence from appropriate animal studies, but this is insufficient to place the substance in category 2.

6. *Other data relevant to risk evaluation*

Indicate if there are any data relevant to risk evaluation and give a short summary of the results including:

6.1 *Degradability*

- Biodegradability
- Biotransformation
- Stability in air
- Stability in water
- Stability in soil

Summary of 5.6.

Reference Nos

□□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□
□□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□ □□

8. OTHER DATA RELEVANT TO RISK EVALUATION

6.1 *Degradability data*

- Biodegradability ☐
- Biotransformation ☐
- Stability in air ☐
- Stability in water ☐
- Stability in soil ☐

Reference Nos

□□ □□ □□ □□ □□
□□ □□ □□ □□ □□
□□ □□ □□ □□ □□
□□ □□ □□ □□ □□
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Summary of 5.6

Carcinogenicity

Note any differences in tumour induction between species or routes of exposure and the influence of dose on tumour incidence. Refer to information on mechanisms of action and metabolic and pharmacokinetic data relevant to carcinogenic activity in species tested. Summarise similarities and differences between effects in animals and findings in men, giving references.

Mutagenicity

Note similarities and differences between results of the various in vitro tests and the effects of metabolic activation of the systems. Compare findings in in vitro systems with those in in vivo systems; comment on the reasons for any differences giving references where possible.

Toxicity to reproduction

Note the type(s) of abnormality occurring in the mothers and young and the dosage levels inducing such abnormalities; in particular note where abnormalities occur at exposure levels lower than those toxic to the mother.

6. OTHER DATA RELEVANT TO RISK EVALUATION

6.1 *Degradability data*

Indicate further evidence for destructive processes showing any degradation potential to the substance not yet specified in 3. The substance may be degraded biologically or physico-chemically (e.g. photooxidation, hydrolysis etc).

Please group available data according to the environmental compartment (water-soil-air) where they have been measured. Give a short summary of the essential data relevant to risk evaluation. Provide all available references in support.

Provide references to experimental studies on man and clinical and epidemiological studies on the substance. In the summary comment, giving references where possible, on the strengths and weaknesses of the studies. Note whether exposure was to the substance alone; where not, the other substances should be noted.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	100
---	---	---	---	---	---	---	---	---	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	----	-----

Summary of 6.12

Note that if data are available for entries 2.1 to 6.12, then these data *must* be entered

Note, giving references, similarities of the substance to others of similar composition or physico-chemical activity which may shed light on the risks of the substance. Where physico-chemical properties of the substance (e.g. particle size of dusts or volatility) may influence profoundly the risks, these should be noted.

APPENDIX 2

Draft - Data Set of EEC/OECD proposal
Harmonised Electronic Data Input Set

EEC/OECD Draft Proposal on a Harmonised Electronic Data Input Set

Important General Information

The EEC/OECD data Input Set is still being developed in order to harmonise existing electronic data banks such as OECD and IRPTC. At the time of publication of these guidelines, this data set has no official status.

This questionnaire and the available data to be entered follows a standardised electronic input set. If more than one study (e.g. for acute toxicity) exists, separate sets of the corresponding section must be used for each study. When the glossary term corresponds to the available data, then this specific term must be used. (In the final version of the data set the glossary terms will be replaced by codes). When the glossary does not contain the specific term needed, then this has to be addressed under 'Remarks'.

updated 30 September 1990

COMMISSION AND OECD DRAFT PROPOSAL ON AHARMONIZED ELECTRONIC DATA INPUT SET1 General Information

1.1 Name of Substance: _____ CEC, OECD
 Use the IUPAC NAME

1.2 EINECS No: _____ CEC

1.3 CAS No: _____ CEC, OECD

1.4 Synonyms a: _____ CEC, OECD
 b: _____
 c: _____
 d: _____
 e: _____
 f: _____
 g: _____
 h: _____
 i: _____
 k: _____

Synonym a = Name used in the company/Country
 Synonym b = CAS name

1.5 Purity: _____ CEC, OECD
 a _____ b _____ c _____ % weight/weight

a: glossary: <, <=, =, >, >=, ca
 b: numeric value or lower value
 c: upper value

1.6 Impurities _____ CEC, OECD

1.6.1 a IUPAC name of impurity : _____

b Percentage: a _____ b _____ c _____ %
 a: glossary: <, <=, =, >, >=, ca
 b: numeric value or lower value
 c: upper value

c EINECS NO : _____ d CAS No : _____

1.6.2 a IUPAC name of impurity : _____

b Percentage: a _____ b _____ c _____ %
 a: glossary: <, <=, =, >, >=, ca
 b: numeric value or lower value
 c: upper value

c EINECS NO : _____ d CAS No : _____

1.4 Synonyms

Only synonyms e.g. ACETONE, ISOPHORONE etc. not trade names.

1.5 Purity

Purity according to technical specifications.

1.6.3 a IUPAC name of impurity : _____

b Percentage: a _____ b _____ c _____ %
 a: glossary: <, <=, =, >, >=, ca
 b: numeric value or lower value
 c: upper value

c EINECS NO : _____ d CAS No : _____

1.6.4 a IUPAC name of impurity : _____

b Percentage: a _____ b _____ c _____ %
 a: glossary: <, <=, =, >, >=, ca
 b: numeric value or lower value
 c: upper value

c EINECS NO : _____ d CAS No : _____

1.6.5 a IUPAC name of impurity : _____

b Percentage: a _____ b _____ c _____ %
 a: glossary: <, <=, =, >, >=, ca
 b: numeric value or lower value
 c: upper value

c EINECS NO : _____ d CAS No : _____

1.7 Additives

OECD

1.71 a IUPAC name of additive : _____

b Percentage: a _____ b _____ c _____ %
 a: glossary: <, <=, =, >, >=, ca
 b: numeric value or lower value
 c: upper value

c EINECS NO : _____ d CAS No : _____

1.72 a IUPAC name of additive : _____

b Percentage: a _____ b _____ c _____ %
 a: glossary: <, <=, =, >, >=, ca
 b: numeric value or lower value
 c: upper value

c EINECS NO : _____ d CAS No : _____

1.73 a IUPAC name of additive : _____

b Percentage: a _____ b _____ c _____ %
 a: glossary: <, <=, =, >, >=, ca
 b: numeric value or lower value
 c: upper value

c EINECS NO : _____ d CAS No : _____

No additional comments

1.8 Molecular Formula : _____ CEC, OECD

1.9 Structural Formula (if possible, Smiles code)
CEC, OECD

1.10 Type of substance _____ CEC, OECD
Glossary:

inorganic _____
organic _____
organometallics _____
element _____
natural substance _____
petroleum product _____

1.11 Name of Producer ☐ yes _____ Name of Sponsor Country ☐ yes
(Name of Contact Point) _____
CEC, OECD

Address: street _____ No _____
Town _____ Postal Code _____ Cedex _____
Country _____ Code _____ Telephone _____ Ext. _____
Telex _____ Telefax _____

1.12 Name of Importer ☐ yes _____ Name of Lead Organisation ☐ yes
CEC, OECD

Address: street _____ No _____
Town _____ Postal Code _____ Cedex _____
Country _____ Code _____ Telephone _____ Ext. _____
Telex _____ Telefax _____

1.13 Quantity produced or imported, greater than 1000 tonnes per year CEC, OECD
produced: a _____ b _____ imported: a _____ b _____

a: glossary: tonnes/year Year: _____
b: glossary:

1.000	-	5.000
5.000	-	10.000
10.000	-	50.000
50.000	-	100.000
100.000	-	500.000
500.000	-	1.000.000
more than	-	1.000.000

1.13 Quantity produced or imported, greater than 1000 tonnes per year

Indicate if the greatest amount produced is exported outside the EEC.

A B C D E F

1.21 Use Pattern

CEC, OECD

Main Category : _____

Glossary:

use in closed system
 use resulting in inclusion or into/onto matrix
 non dispersive use
 wide spread use

Use category _____

Glossary:

Absorbents and adsorbents
 Adhesive and/or binding agents
 Aerosol propellants
 Anti-condensation agents
 Anti-freezing agents
 Anti-set-off and anti-adhesive agents
 Anti-static agents
 Bleaching agents
 Cleaning/washing agents and disinfectants
 Colouring agents
 Complexing agents
 Conductive agents
 Construction materials
 Heat transferring agents
 Corrosive inhibitors
 Cosmetics
 Dustbinding agents
 Semiconductors
 Explosives
 Fertilizers
 Fillers
 Fixing agents
 Flame retardants and fire preventing agents
 Flotation agents
 Flux agents for casting
 Foaming agents
 Food additives
 Friction agents
 Fuel and fuel additives
 Electroplating agents
 Hydraulic fluids
 Impregnation agents
 Insulating agents
 Intermediates
 Laboratory chemicals
 Lubricants
 Odour agents
 Oxidizing agents
 Paint and varnish removers
 Paints, lacquers and varnishes, additives
 Pesticides
 pH-regulating agents
 Pharmaceuticals
 Photochemicals
 Plastic additives

1.21 Use Pattern

Use Pattern see general comments on page 7 and 8 of this report.

Process regulators
 Reducing agents
 Softeners
 Soldering agents
 Solvents
 Stabilizers
 Surface-active agents
 Tanning agents
 Viscosity adjustors
 Vulcanising agents
 Welding auxiliaries
 Other or unknown function

Remarks: _____

1.22 Source of exposure (e.g. Disposal) OECD

Describe sources of potential human or environmental exposure including workplace concentrations and emission data (in % release), if available, for both manufacturing and user areas.

Reference Nos

Remarks: _____

1.23 Occupational Exposure Limit Values OECD

Exposure Limit Value a _____ b _____ c _____

- a. numerical value
- b: glossary: %, mg/g, mg/m³, ml/m³, ug/m³, ug/dl, ug/l
- c: glossary: TLV, MAK, etc

Short Term Exposure Limit Value

a _____ b _____ c _____ d _____ e _____

- a. numerical value
- b: glossary: %, mg/g, mg/m³, ml/m³, ug/m³, ug/dl, ug/l
- c: numerical value
- d: glossary: min, h,
- e: interval per working day

1.23 Occupational Exposure Limit Values

If a TLV, MAK etc value does not exist give the internal hygiene standard of the producer company if available.

- 1.24 Has the complete Data Set already been submitted
by another manufacturer or importer? CEC

 Glossary: yes, no, do not known

- a) If yes, then indicate the manufacturer or importer
who is responsible for having filled in and returned
the completed Data Set

Name of the responsible manufacturer or importer
.....
Address: street No....
Town Postal Code Cedex
Country Code Telephone Ext..
Telex Telefax

- b. if no or do not known, continue to fill the Data Set

- 1.25 Specify if you are acting on behalf of
other concerned manufacturer or importer CEC

 Glossary: yes, no

- 1.26 Other Remarks: (e.g. disposal)
-
-

No additional comments

2 Physical-Chemical Data

updated 30 September 1990

2.1 Melting pointCEC, OECD
References Nos

Value: a..... b..... c.....
 a: glossary: <, <=, =, >, >=, c (circa) — — —
 b: numerical value: — — —
 c: glossary: degree C — — —

Range of values: a..... b.....
 a: lower value — — —
 b: upper value — — —

Decomposition:
 glossary: yes, no, ambiguous — — —

Sublimation:
 glossary: yes, no, ambiguous

Method:**Glossary:**

OECD Guide-line 102, Year: —
 Directive 84/449/EEC, A.2
 Other (see remarks)

GLP:

.....
 Glossary:
 yes, no, no data

Remarks: _____

2.2 Boiling pointCEC, OECD
References Nos

Value: a..... b..... c.....
 a: glossary: <, <=, =, >, >=, c (circa) — — —
 b: numerical value: — — —
 c: glossary: degree C — — —

Range of values: a..... b.....
 a: lower value — — —
 b: upper value — — —

Pressure: a..... b.....
 a: numerical value:
 b: glossary: hPa

Decomposition:
 glossary: yes, no, ambiguous

Method:**Glossary:**

OECD Guide-line 103, Year: —
 Directive 84/449/EEC, A.1
 Other (see remarks)

No additional comments

GLP:
 Glossary:
 yes, no, no data

Remarks: _____

2.3 Density

OECD
 References Nos

Value: a.....	b.....	c.....	_____	_____	_____
a: glossary: <, <=, =, >, >=, c (circa)			_____	_____	_____
b: numerical value:			_____	_____	_____
c: glossary: g/cm ³ , no unit of measure			_____	_____	_____
Range of values: a.....	b.....		_____	_____	_____
a: lower value			_____	_____	_____
b: upper value			_____	_____	_____
Temperature: a.....	b.....		_____	_____	_____
a: numerical value:			_____	_____	_____
b: glossary: degree C			_____	_____	_____

Method:

Glossary:
 OECD Guide-line 109, Year: _____
 Directive 84/449/EEC, A.3
 Other (see remarks)

GLP:
 Glossary:
 yes, no, no data

Remarks: _____

2.4 Vapour pressure

CEC, OECD
 References Nos

Value: a.....	b.....	c.....	_____	_____	_____
a: glossary: <, <=, =, >, >=, c (circa)			_____	_____	_____
b: numerical value:			_____	_____	_____
c: glossary: hPa			_____	_____	_____
Range of values: a.....	b.....		_____	_____	_____
a: lower value			_____	_____	_____
b: upper value			_____	_____	_____
Temperature: a.....	b.....		_____	_____	_____
a: numerical value:			_____	_____	_____
b: glossary: degree C			_____	_____	_____

Method:

Glossary:
 OECD Guide-line 104, Year: _____
 Directive 84/449/EEC, A.4
 Calculated
 Other (see remarks)

No additional comments

GLP:
 Glossary:
 yes, no, no data

Remarks: _____

2.5 Partition Coefficient (log P_{OW})

CEC, OECD
 References Nos

Value: a..... b.....
 a glossary: <, <=, =, >, >=, c (circa) _____
 b numerical value: _____

Temperature: a..... b.....
 a: numerical value: _____
 b: glossary: degree C _____

Method: _____
 Glossary:
 Directive 84/449/EEC, A.8
 Calculated according to Leo and Hansch
 OECD Guide-line 107, Year: _____
 OECD Guide-line 117, Year: _____
 Calculation: _____
 other (see remarks) _____

GLP:
 Glossary:
 yes, no, no data

Remarks: _____

No additional comments

2.6 Water Solubility

CEC, OECD
 References Nos

Value: a..... b..... c.....
 a: glossary: <, <=, =, >, >=, c (circa) _____
 b: numerical value: _____
 c: glossary: g/l _____
 mg/l _____
 Vol% _____
 other (see remarks) _____

Range of values: a..... b.....
 a: lower value _____
 b: upper value _____

Temperature: a..... b.....
 a: numerical value: _____
 b: glossary: degree C _____

pH value _____ concentration _____ pKa value _____ at 25 °C

Temperature: a..... b.....
 a: numerical value: _____

b: glossary: degree C

Method:

Glossary:

OECD Guide-line 105, Year: _____
 Directive 84/449/EEC, A.6
 Calculated
 Other (see remarks)

GLP:

.....
 Glossary:
 yes, no, no data

Remarks: _____

No additional comments

2.7 Flash Point

CEC, OECD
 References Nos

Value: a:..... b:..... c:.....
 a: glossary: <, <=, =, >, >=, c (circa) _____
 b: numerical value: _____
 c: glossary: degree C _____

Type: open cup _____ closed cup _____

Method

Glossary:

Directive 84/449/EEC, A.9
 other (see remarks)

GLP:

.....
 Glossary:
 yes, no, no data

Remarks: _____

2.8 Auto Flammability

CEC, OECD
 References Nos

Value: a:..... b:..... c:.....
 a: glossary: <, <=, =, >, >=, c (circa) _____
 b: numerical value: _____
 c: glossary: degree C _____

Range of values: a:..... b:.....

a: lower value
 b: upper value

Pressure: a:..... b:.....

a: numerical value
 b: glossary: hPa

Method:
 Glossary:
 Directive 84/449/EEC, A.15
 Other (see remarks)

GLP:
 Glossary:
 yes, no, no data

Remarks: _____

No additional comments

2.9 Flammability

	CEC, OECD References Nos
Value: a..... b..... c.....	_____
a: glossary: <, <=, =, >, >=, c (circa)	_____
b: numerical value:	_____
c: glossary: degree C	_____
Range of values: a..... b.....	_____
a: lower value	_____
b: upper value	_____
Pressure: a..... b.....	_____
a: numerical value	_____
b: glossary: hPa	_____

Method:
 Glossary:
 Directive 84/449/EEC, A 10 (solids)
 Directive 84/449/EEC, A 11 (gases)
 Directive 84/449/EEC, A 12
 Directive 84/449/EEC, A 15 (solids and liquids)
 Other (see remarks)

GLP:
 Glossary:
 yes, no, no data

Remarks: _____

2.10 Explosive Properties

	CEC, OECD References Nos
Method: Glossary: Directive 84/449/EEC, A 14 Other (see remarks)	_____ _____ _____
Explosive Properties: _____ Glossary yes, no	_____ _____
GLP: Glossary: yes, no, no data	_____

Remarks: _____

2.11 Oxidizing PropertiesCEC, OECD
References Nos

Method:

Directive 84/449/EEC, A 17
Other (see remarks)____

Oxidizing Properties: ____

Glossary: yes, no

GLP:

.....

Glossary:

yes, no, , no data

Remarks: _____

2.12 Other Data and RemarksCEC, OECD
References Nos

Remarks: _____

No additional comments

3 Environmental Fate

updated 30 September 1990

and Pathways**3.1 Stability**

CEC, OECD

3.1.1 Photodegradation

CEC, OECD

References Nos

Test substance: _____

Glossary: substance as prescribed by 1.1 - 1.8
 other _____ purity _____ %
 no data

Type: _____

Glossary: air
 soil
 water

Method: _____ Year: _____

Glossary:

calculated (see remarks) _____
 EPA Guide-line subdivision N 161-2 1982 _____
 OECD Guide-line draft _____
 other (see remarks)

Light source:

Glossary:

Xenon burner
 other

Wave lengths: a _____ b _____ nm

a: lower value
 b: upper value

Rel. Intensity: a _____ b _____
 based on intensity of sunlight a: lower value
 b: upper value

Quantum yield a _____

Rate constant (K_{OH}): _____ ($\text{cm}^3 \cdot \text{molecule}^{-1} \cdot \text{sec}^{-1}$)OH Radical concentration: _____ ($\text{molecule}/\text{cm}^3$)T_{1/2}: a _____ b _____ c _____ d _____

a: glossary: <, <=, =, >, >=, c (circa)
 b: lower value
 c: upper value
 d: glossary: hours, days, months

Temperature: a _____ b _____

a: numeric value
 b: glossary: degree C

3. Environmental Fate and Pathways

If possible use values described in the test methods. Chemicals that pass such tests are therefore believed to be so readily biodegradable that they will be easily degraded in most environmental aerobic fresh waters or in sewage treatment plants (ECETOC 1985. T.R. No 18 "Harmonisation of Ready Biodegradability Tests").

Other tests intended to find out whether chemicals are eliminated in waste water treatment plants (Zahn-Wellens-Test, Activated Sludge Simulation Test etc.) are described in Council Directive 87/302/EEC.

3.1 Stability**3.1.1 Photodegradation**

Give information concerning direct or indirect photodegradation in air, water and soil (experimental conditions, half-life, degradation etc). Additional information should be given under "Remarks".

% of degradation after a.... days b..... c..... d.....

a: numerical value
b: glossary: <, <=, =, >, >=, c (circa)
c: lower value
d: upper value

GLP: _____

Glossary: yes, no, no data

Remarks: _____

3.1.2 Stability in Water (e.g. hydrolysis) CEC, OECD
References Nos

Test substance: _____

Glossary: substance as prescribed by 1.1 - 1.8
other _____ purity _____ %
no data

Test type: _____

Glossary: abiotic
biotic (e.g. sediment)

Method: _____ Year: _____

Glossary: _____
OECD Guide-line, 111
Directive 84/449/EEC, C 10
other (see remarks)

Rate constant K _____ sec⁻¹

		numerical value	duration	temperature
t1/2	pH5	a_____ b_____ c_____	d_____	e_____ f_____
t1/2	pH7	a_____ b_____ c_____	d_____	e_____ f_____
t1/2	pH9	a_____ b_____ c_____	d_____	e_____ f_____
t1/2	pH__	a_____ b_____ c_____	d_____	e_____ f_____

a: glossary: <, <=, =, >, >=, c (circa)
b: lower value
c: upper value
d: glossary: min, hour, day, month
e: numeric value
f: glossary: degree C

3.1.2 Stability in Water

Give information concerning hydrolysis, half-life in water and resulting degradation products (incl. CAS number, name, percentage). Additional information should be given under "Remarks".

% of degradation after a.... days b..... c..... d.....

a: numerical value
b: glossary: <, <=, =, >, >=, c (circa)
c: lower value
d: upper value

Degradation products: _____

GLP: _____

Glossary: yes, no, no data

Remarks: _____

3.1.3 Stability in soil

CEC, OECD

Test substance: _____ References Nos _____

Glossary: substance as prescribed by 1.1 - 1.8
other _____ purity _____ %
no data

Test type: _____
Glossary: laboratory
field trial

Method: _____ Year: _____

Glossary: OECD Guide-line 304A
other (see remarks)

Test concentration: a _____ b _____
a: numeric value
b: glossary: ppm, other (see remarks)

Radiolabel: _____
Glossary: yes, no

Soil temperature: a _____ b _____
a: numeric value
b: glossary: degree C

Soil humidity: a _____ b _____
a: numeric value
b: glossary: g water/100g soil

Remarks _____

3.1.3 Stability in soil

Give information concerning stability in soil. Additional information should be given under "Remarks".

soil classification: _____ Year: _____

Glossary: USDA
DIN19863
NF X31-107
other

clay: a _____ b _____ %
silt: a _____ b _____ %
sand: a _____ b _____ %
a: numeric value or lower value
b: upper value

Organic carbon: a _____ b _____ %
a: glossary: <, <=, =, >, >=, c (circa)
b: numeric value

pH: a _____ b _____ c _____
a: glossary: <, <=, =, >, >=, c (circa)
a: numeric or lower value
b: upper value

Cation exchange capacity: a _____ b _____
a: glossary: <, <=, =, >, >=, c (circa)
b: glossary: mequ/100g soil

Microbial biomass: a _____ b _____
a: numeric value
b: Glossary: mg C_{MIKRO}/100g soil

Dissipation time DT50: a _____ b _____ c _____ d _____
a: glossary: <, <=, =, >, >=, c (circa)
b: lower value
c: upper value
d: glossary: hour, day, month

GLP: _____

Glossary: yes, no, no data

Remarks: _____

3.2 Monitoring Data (Environment)

CEC, OECD

Indicate whether the data are measurements of background concentrations: _____ or measurements at contaminated sites: _____

air: _____

surface water: _____

ground water: _____

3.2 Monitoring Data (Environmental)

Note that Data on Biological Effects Monitoring including biomagnification and biotransformation and kinetics in environmental species is to be reported in section 4.7 and 4.8 respectively. Nonetheless concentrations in various compartments should be reported here including negative data. Data on concentrations in the work place or indoor environments should be reported under item 5.11.

Results: Give detailed information, e.g. concentration of the chemical, location and date of measurement, and specify the type of measurement.

soil/sediment: _____

food: _____

biota: _____

References Nos _____

3.3 Transport and Distribution between environmental compartments including estimated environmental concentrations and distribution pathways

3.3.1 Transport (Volatility, Adsorption CEC, OECD Desorption)

Method: _____ Year: _____
Glossary: other (see remarks)

Compartment:

water soil air

water soil air

water soil air

water soil air

Results: _____

References Nos _____

3.3.2 Distribution between environmental compartments CEC, OECD

Method: _____ Year: _____
Glossary: calculated Mackay, Level I
calculated Mackay, Level II
other (see remarks)

Compartments

water soil air biota

water soil air biota

water soil air biota

water soil air biota

3.3 Transport and Distribution between environmental compartments including estimated environmental concentrations and distribution pathways.

3.3.1 Transport

Give information on transport from one compartment to the other (water, soil, air, biota). Additional information should be given under 3.8 "Other Remarks".

3.3.2 Distribution between environmental compartments

Give information on distribution between different compartments (water, soil, air, biota). Additional results should be given under 3.8 "Other Remarks".

Note : In 3.3.1 and 3.3.2 the section "compartments" will be redefined by the EEC/OECD in the final version of the data set.

Results: _____

References Nos _____

3.4 Identification of main mode of degradation in actual use CEC, OECD

Remarks: _____

References Nos _____

3.5 Biodegradation CEC, OECD

Test substance: _____

Glossary: as prescribed by 1.1 - 1.8
 other _____ purity _____ %
 no data

Type of test _____
 Glossary: aerobic, anaerobic

Method: _____ Year: _____
 Glossary: _____

DIN 38409, part 51
 DIN 38412, part 24
 DIN 38412, part 25
 Directive 84/449/EEC, C.3
 Directive 84/449/EEC, C.5
 Directive 84/449/EEC, C.4
 Directive 84/449/EEC, C.6
 Directive 84/449/EEC, C.7
 Directive 87/302/EEC, part C, p 99
 Directive 87/302/EEC, part C, p 106
 Directive 87/302/EEC, part C, p 123
 ISO, 7824
 ISO DP 9408,
 ISO DIS 9493
 ISO Draft, BOD test for insoluble substances
 OECD Guide-line 301 A
 OECD Guide-line 301 B
 OECD Guide-line 301 C
 OECD Guide-line 301 D
 OECD Guide-line 301 E
 OECD Guide-line 302 A
 OECD Guide-line 302 B
 OECD Guide-line 303 A
 ECETOC, Anaerobic
 biodegradation
 other (see remarks)

3.4 Identification of main mode of degradation in actual use.

Give information about the principal degradation route of the product (e.g; via Hydrolysis, Phototolysis etc).

3.5 Biodegradation

Indicate whether evidence exists showing that the substance is biodegradable. If possible use the value of more than one biodegradation test. Provide all available references in support.

Inoculum:

Glossary:

activated sludge	_____
activated sludge, (adapted)	_____
activated sludge, (non-adapted)	_____
of industrial waste water	_____
of industrial waste water (adapted)	_____
of waste water from domestic sewage	_____
of waste water from domestic sewage (adapted)	_____
other (see remarks)	

Concentration a..... b..... related to c.....

a: numerical value:
b: glossary: g/l, mg/l mmol/l, mol/l ug/l
umol/l
c: glossary: CSB, DOC, Test substance

% of degradation after a.... days b..... c..... d.....

a: numerical value
b: glossary: <, <=, =, >, >=, c (circa)
c: lower value
d: upper value

Degradation products: _____

Results:

Glossary:

inherently biodegradable
readily biodegradable
under test conditions no biodegradation
observed
other (see remarks)

Remarks: _____

Zahn-Wellens Test

3	h	a.....	b.....	c.....
7	d	a.....	b.....	c.....
..	..	a.....	b.....	c.....
..	..	a.....	b.....	c.....
..	..	a.....	b.....	c.....

a: glossary: <, <=, =, >, >=, c (circa)
b: lower value
c: upper value

GLP: _____

Glossary: yes, no, no data

Remarks: _____

In biodegradation tests a substance under investigation (the substrate) is contained in a fixed amount of test medium and determined analytically as a function of time (normally 28 days). Biodegradation is due to microorganism inoculated from various sources (ECETOC 1983, T.R. No. 8; "Biodegradation of Ready Biodegradability Tests: An Assessment of the Present Status").

The Modified OECD Screening Test and the Modified AFNOR Test are a kind of DOC Die Away Tests: Biodegradation of the test substance is measured by following a decrease of initially added 20 or 40 mg/l dissolved organic carbon (DOC). Regularly 1 liter test volume is incubated at room temperature in a 2 liter Erlenmeyer flask and aerated by shaking.

In the Modified Sturmtest evolution of CO₂ during the mineralisation of the test compound is quantitated within absorption vessels through which the outcoming gas flushes.

3.6 In those cases where the COD and BOD₅ are available use the BOD₅/COD ratio

CEC

BOD₅

Method: _____ Year: _____ References Nos
 Glossary: Directive 84/449/EEC C 8
 ISO 5815
 DIN 38409 part 51
 DIN 38409 part 52
 other (see remarks)
 BOD₅: a _____ b _____
 Glossary: a; <, <=, =, >=, >, c
 b; numeric value

COD

Method: _____ Year: _____
 Glossary: Directive 84/449/EEC C 9
 ISO DP 6060
 DIN 38409 part 41
 DIN 38409 part 43
 other (see remarks)
 COD: a _____ b _____
 Glossary: a; <, <=, =, >=, >, c
 b; numeric value
 Ratio BOD₅/COD: a _____ b _____
 Glossary: a; <, <=, =, >=, >, c
 b; numeric value
 GLP: _____
 Glossary: yes, no, no data
 Remarks: _____

3.7 Bioaccumulation

CEC, OECD

Test substance: _____ References Nos
 Glossary: as prescribed by 1.1 - 1.8
 other _____ purity _____ %
 no data
 Species: _____
 Glossary: _____

3.6 COD and BOD₅

If only COD (Chemical Oxygen Demand) and BOD₅ values (Biochemical Oxygen Demand after 5 days) are available, give BOD₅/COD ratio and provide the available reference(s) in support. Chemicals with BOD values in the range of 20% COD or even less need to be investigated further by biodegradation tests.

The respirometric methods (e.g. Closed Bottle Test, Modified MITI Test and the BOD₅ Test) substantiate the oxidation process of the biodegraded compound by recording the oxygen consumption during the test period. Biodegradation is expressed as BOD₅/COD ratio.

3.7 Bioaccumulation

Give the bioconcentration factor BCF (factor describing the relation between the concentration of a chemical in water and its concentration in the organism after equilibration). Additional information such as depuration kinetics, metabolism, correlation formulas of calculated values should be given under 'Remarks'.

Method: _____ Year: _____

Glossary:

OECD Test Guide-line 305 A
 OECD Test Guide-line 305 B
 OECD Test Guide-line 305 C
 OECD Test Guide-line 305 D
 OECD Test Guide-line 305 E
 Calculated (see remarks)
 other (see remarks)

Remarks: _____

Bioconcentration Factor (log BCF)

Value: a..... b..... c.....
 a: glossary: <, <=, =, >, >=, c (circa) _____
 b: numerical value or lower value _____
 c: upper value _____

GLP: _____

Glossary: yes, no, no data

Remarks: _____

3.8 Other remarks

CEC, OECD

Remarks: _____

References Nos: _____

3.8 Other Remarks

Give any other relevant information which has not already been described under previous headings of section 3.

4 Ecotoxicity

updated 30 September 1990

4.1 Toxicity to Fish (acute and prolonged)

CEC, OECD

Test substance: _____

Glossary: as prescribed by 1.1 - 1.8
 other _____ purity _____ %
 no data _____

References Nos

Type: _____

Glossary:
 static
 semistatic
 flow through
 field observation
 other

Species of fish _____

Glossary:
 Alburnus alburnus
 Brachydanio rerio
 Carassius auratus
 Cyprinodon variegatus
 Carpinus carpio
 Esox lucius
 Fundulus heteroclitus
 Gambusia affinis
 Lepomis macrochirus
 Leuciscus idus
 Oryzias latipes
 Petromyzon fluviatilis
 Phoxinus phoxinus
 Pimephales promelas
 Poecilia (Lebistes) reticulata
 Rasbora heteromorpha
 Salmo gairdneri
 Salmo trutta
 other (see remarks)

Method: _____ Year: _____

Glossary:
 Directive 84/449/EEC, C.1
 ISO 7346/1-3
 OECD Guide-line 203
 other methods (see remarks)

Exposure period a _____ b _____

a: numerical value:
 b: glossary: days; hours

4. Ecotoxicity

Common test methods for investigation of ecological data are prescribed in Annex V of Council Directive 79/831/EEC of 18 September 1979, as laid down in Commission Directives 84/449/EEC of 24 April 1984 and 87/302/EEC of 18 November 1987. These test methods are usually based on OECD Test Guidelines. Please note test results according to these guidelines. Results from test methods not standardised by normed guidelines should be quoted under section 4.9.

4.1 Toxicity to Fish (acute and prolonged)

Indicate whether toxic effect on fish were found. Give the results as NOEC, LCO, LC50, LC100 and others together with the duration of the test (in hours). If there is a range available indicate minimum and maximum. Comments on a test e.g. use of dispersants/solvents, effect of pH on toxicity, closed or open test systems, evaluation of the dose-response-curve, narcotic effects etc. should be given under "Remarks". Provide all available references in support.

Unit of measurement _____

Glossary:

g/l
mg/l
mmol/l
mol/l
ug/l
umol/l

NOEC	Fish	a.....	b.....	c.....
LC0	Fish	a.....	b.....	c.....
LC50	Fish	a.....	b.....	c.....
LC100	Fish	a.....	b.....	c.....
.....	Fish	a.....	b.....	c.....

a: glossary: <, <=, =, >, >=, c (circa)
b: lower value
c: upper value

GLP: _____

glossary: yes, no, no data

Remarks: _____

4.2 Toxicity to daphnia and other aquatic invertebrates (acute and prolonged)

CEC, OECD

References Nos

Test substance: _____

Glossary: as prescribed by 1.1 - 1.8

other _____ purity _____ %
no data

Species _____

Glossary:

Artemia salina
Ceriodaphnia spec.
Daphnia magna
Daphnia pulex
Nitocra spinipes
other

Method: _____ Year: _____

Glossary:

Directive 84/449/EEC, C.2
ISO 6341 15
OECD Guide-line 202
other methods (see remarks)

4.2 Toxicity to daphnia and other aquatic invertebrates (acute and prolonged)

Indicate whether toxic effects on daphnia or other invertebrates were found. Give the results as NOEC, ECO, EC50, EC100 or other values together with the duration of the test (in hours). If there is a range of values indicate minimum and maximum.

Comments on a test e.g. use of dispersants/solvents, effect of pH on toxicity, closed or open test system, evaluation of the dose-response-curve, narcotic effects should be given under "Remarks". Provide all available references in support.

Exposure period a _____ b _____
 a: numerical value:
 b: glossary: days; hours

Unit of measurement _____

Glossary:

g/l
 mg/l
 mmol/l
 mol/l
 ug/l
 umol/l

NOEC	aqua inv	a.....	b.....	C.....
EC0	aqua inv	a.....	b.....	C.....
EC50	aqua inv	a.....	b.....	C.....
EC100	aqua inv	a.....	b.....	C.....
.....	aqua inv	a.....	b.....	C.....

a: glossary: <, <=, =, >, >=, c (circa)
 b: lower value
 c: upper value

GLP: _____

glossary: yes, no, no data

Remarks: _____

4.3 Toxicity to algae

CEC, OECD

Test substance: _____

References Nos

Glossary: as prescribed by 1.1 - 1.8

other _____ purity _____ %

no data

Species of algae _____

Glossary:

Ankistrodesmus falcatus
 Chlorella pyrenoidosa
 Chlorella vulgaris
 Microcystis aeruginosa
 Phaeodactylum tricornutum
 Scenedesmus quadricauda
 Scenedesmus subspicatus
 Selenastrum capricornutum
 Skeletonema costatum
 other

4.3 Toxicity to algae

Indicate whether toxic effects on algae were found. Give the results as EC10, EC50, NOEC, LOEC and others together with the duration of the test (in hours). If there is a range available, indicate min. and max. Comments on a test e.g. use of dispersants/solvents, effect of pH on toxicity, closed or open test system, evaluation of the dose-response-curve, EC100, bleaching of algae, effects on photosynthesis, substance incorporation into algal biomass should be given under "Remarks". Provide all available references in support.

Method: _____ Year: _____
 Glossary:
 Directive 87/302/EEC, part C, p 89
 ISO 8692
 OECD Guide-line 201
 DIN 38412 part 9
 other methods (see remarks)

Exposure period a _____ b _____
 a: numerical value:
 b: glossary: days, hours

Unit of measurement _____
 Glossary:
 g/l
 mg/l
 mmol/l
 mol/l
 ug/l
 umol/l

EC10	algae	a.....	b.....	C.....
EC50	algae	a.....	b.....	C.....
NOEC	algae	a.....	b.....	C.....
LOEC	algae	a.....	b.....	C.....
....	algae	a.....	b.....	C.....

a: glossary: <, <=, =, >, >=, c (circa)
 b: lower value
 c: upper value

GLP: _____
 glossary: yes, no, no data

Remarks: _____

4.4 Toxicity to bacteria

CEC, OECD

Test substance: _____

References Nos

Glossary: as prescribed by 1.1 - 1.8
 other _____ purity _____ %
 no data

Species _____

Glossary:
 Bacillus subtilus
 activated sludge
 activated sludge of an industrial sewage
 activated sludge of a domestic sewage
 Escherichia coli
 Nocardia spec.
 Photobacterium phoshoreum
 Pseudomonas fluorescens

4.4 Toxicity to bacteria

Indicate whether toxic effects on bacteria were found. Give the results as EC10, EC50 and others together with the duration of the test (in hours). If there is a range available, indicate min. and max. Comments on a test e.g. use of dispersants/solvents, effect of pH on toxicity, closed or open test system, evaluation of the dose-response curve, should be given under "Remarks". Provide all available references in support.

Pseudomonas putida
 Salmonella typhimurium
 other

Method: _____ Year: _____

Glossary:

Directive 87/302/EEC, part C, p 118
 OECD Guide-line 209
 DIN 38412 part 27
 DIN 38412 part 8
 ISO 8192
 ETAD, Fermentation tube method
 Fermentation tube method
 (see remarks)
 ISO 9509
 other methods (see remarks)

Exposure period a _____ b _____

a: numerical value:

b: glossary: hours, min

Unit of measurement _____

Glossary:

g/l
 mg/l
 mmol/l
 mol/l
 ug/l
 umol/l

EC10	micro org	a.....	b.....	c.....
EC50	micro org	a.....	b.....	c.....
....	micro org	a.....	b.....	c.....

a: glossary: <, <=, =, >, >=, c (circa)

b: lower value

c: upper value

GLP: _____

glossary: yes, no, no data

Remarks: _____

4.5 Chronic Toxicity to aquatic organism

OECD

4.5.1 Chronic Toxicity to Fish

OECD

References Nos

Test substance: _____

Glossary: as prescribed by 1.1 - 1.8
 other _____ purity _____ %
 no data

_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

4.5.1 Chronic toxicity to fish

Indicate whether chronic toxic effects on fish (growth rate, reproduction rate) were found. Give the results as EC50, NOEC, LOEC and others together with the duration of the test. If there is a range available indicate min. and max. Comments on a test e.g; use of dispersants/solvents, effect of pH on toxicity, closed or open test system, evaluation of the dose-response-curve, narcotic effects etc. should be given under "Remarks". Provide all available references in support.

Growth length of fish (larve)

EC50	a.....	b.....	c.....
NOEC.	a.....	b.....	c.....
LOEC.	a.....	b.....	c.....
.....	a.....	b.....	c.....

a: glossary: <, <=, =, >, >=, c (circa)

b: lower value

c: upper value

Results: Remarks: _____

GLP: _____

glossary: yes, no, no data

Remarks: _____

4.5.2 Chronic Toxicity to daphnia and aquatic invertebrates

OECD
References Nos

Test substance: _____

Glossary: as prescribed by 1.1 - 1.8
other _____ purity _____ %
no data

Species of daphnia _____

Glossary:

Artemia salina
Ceriodaphnia spec.
Daphnia magna
Daphnia pulex
Nitocra spinipes
other

Method: _____ Year: _____

Glossary:

OECD Guide-line 202, Part 2
other methods (see remarks)

Exposure period: a _____ b _____

a: numerical value:

b: glossary: days

Unit of measurement _____

Glossary:

g/l
mg/l
mmol/l
mol/l
ug/l
umol/l

4.5.2 Chronic toxicity to daphnia and aquatic invertebrates

Indicate whether chronic toxic effects on daphnia or other aquatic invertebrates (reproduction rate, mortality of parents) were found. Give the results as EC50 (concentration with 50% effects), NOEC, LOEC and others together with the duration of the test. If there is a range available indicate min. and max. Comments on a test e.g. use of dispersants/solvents, effect of pH on toxicity, closed or open test system, evaluation of the dose-response-curve, should be given under "Remarks". Provide all available references in support.

Reproduction rate

EC50	a.....	b.....	c.....
NOEC	a.....	b.....	c.....
LOEC	a.....	b.....	c.....
_____	a.....	b.....	c.....

a: glossary: <, <=, =, >, >=, c (circa)

b: lower value

c: upper value

Unit of measurement _____

Glossary:

g/l

mg/l

mmol/l

mol/l

ug/l

umol/l

Mortality of parents

EC50	a.....	b.....	c.....
NOEC.	a.....	b.....	c.....
LOEC	a.....	b.....	c.....
_____	a.....	b.....	c.....

a: glossary: <, <=, =, >, >=, c (circa)

b: lower value

c: upper value

Results: Remarks: _____

GLP: _____

glossary: yes, no, no data

4.6 0 Toxicity to terrestrial organisms

CEC, OECD

4.6.1 Toxicity to soil dwelling organisms

References Nos

Test substance: _____

Glossary: as prescribed by 1.1 - 1.8

other _____ purity _____ %

no data

4.6.1 Toxicity to soil dwelling organisms

Indicate whether toxic effects on soil dwelling organism were found. Give the results as NOEC, LCO, LC50, LC100 and others together with the duration of the test. if there is a range available, indicate min. and max. Comments on a test e.g. use of dispersants/solvents, effect of pH on toxicity, closed or open test system, evaluation of the dose-response curve, should be given under "remarks". Provide all available references in support.

Type: _____
 Glossary:
 Filter paper
 artificial soil

Species _____

Glossary:
 Eisenia foetida
 other

Method: _____ Year: _____

Glossary:
 OECD Guide-line, 207
 Directive 87/302/EEC, part C, p 95
 other
 see (remarks)

Exposure period a _____ b _____
 a: numerical value:
 b: glossary: days; hours

Unit of measurement _____

Glossary:
 g/l
 mg/l
 mmol/l
 mol/l
 ug/l
 umol/l

NOEC	terrestrial. org	a.....	b.....	C.....
LC0	terrestrial. org	a.....	b.....	C.....
LC50	terrestrial. org	a.....	b.....	C.....
LC100	terrestrial. org	a.....	b.....	C.....
.....	terrestrial. org	a.....	b.....	C.....

a: glossary: <, <=, =, >, >=, c (circa)
 b: lower value
 c: upper value

GLP: _____
 glossary: yes, no, no data

Remarks: _____

4.6.2 Toxicity to plants

CEC, OECD

Test substance: _____ References Nos

Glossary: as prescribed by 1.1 - 1.8
 other _____ purity _____ %
 no data _____

4.6.2 Toxicity to plants

Indicate whether toxic effects on plants were found. Give the results as NOEC, EC50, LC50 or other values together with the duration of the test. If there is a range of values, indicate min. and max. Comments on a test e.g. use of dispersants/solvents, effect of pH on toxicity, evaluation of the dose-response-curve, should be given under "Remarks". Provide all available references in support.

Species _____

Glossary:

Category 1

Test species

Lolium perenne	rye-grass
Oryza sativa	rice
Avena sativa	oat
Triticum aestivum	wheat
Sorghum bicolor	sorghum

Category 2

Brassica alba	mustard
Brassica napus	rape
Raaphanus sativus	radish
Brassica rapa	turnip
Brassica campestris	Chinese cabbage
var, chinensis	

Category 3

Vicia sativa	vetch
Phaseolus aureus	mung bean
Trifolium pratense	red clover
trifolium ornitho-	fenugreek
podiioides	
Lactuca sativa	lettuce
Lepidium sativum	cress
other	

Method: _____ Year: _____

Glossary:

OECD Guide-line, 208
other (see remarks)

Exposure period a _____ b _____

a: numerical value:

b: glossary: days; hours

Unit of measurement _____

Glossary:

g/l
mg/l
mmol/l
mol/l
ug/l
umol/l

Category 1

NOEC	terrt. plants	a.....	b.....	C.....
EC0	terre. plants	a.....	b.....	C.....
EC50	terre. plants	a.....	b.....	C.....
EC100	terre. plants	a.....	b.....	C.....
.....	terre. plants	a.....	b.....	C.....
.....	terre. plants	a.....	b.....	C.....

Unit of measurement _____

Glossary:

g/l
mg/l
mmol/l
mol/l
ug/l
umol/l

Category 2

NOEC	terrt. organism	a.....	b.....	c.....
EC0	terre. organism	a.....	b.....	c.....
EC50	terre. organism	a.....	b.....	c.....
EC100	terre. organism	a.....	b.....	c.....
.....	terre. organism	a.....	b.....	c.....
.....	terre. organism	a.....	b.....	c.....

Unit of measurement _____

Glossary:

g/l
mg/l
mmol/l
mol/l
ug/l
umol/l

Category 3

NOEC	terrt. organism	a.....	b.....	c.....
EC0	terre. organism	a.....	b.....	c.....
EC50	terre. organism	a.....	b.....	c.....
EC100	terre. organism	a.....	b.....	c.....
.....	terre. organism	a.....	b.....	c.....
.....	terre. organism	a.....	b.....	c.....

a: glossary: <, <=, =, >, >=, c (circa)
b: lower value
c: upper value

GLP: _____

glossary: yes, no, no data

Remarks: _____

4.6.3 Other species (including avians)

OECD

Test substance: _____

References Nos

Glossary: as prescribed by 1.1 - 1.8

other _____ purity _____ %
no data

4.6.3 Toxicity to other species (including avians)

Indicate whether toxic effects on birds were found. Give comments on a test e.g. use of dispersants/solvents, effect of pH on toxicity, evaluation of the dose-response-curve and application method under "Remarks. Provide all available references in support.

Species: _____

Glossary:

Anas platyrhynchos (mallard duck)
 Colinus virginianus (bobwhite quail)
 Columba livia (pigeon)
 Coturnix coturnix (Japanese quail)
 japonica
 Phasianus colchicus (ring necked pheasant)
 Alectoris rufa (redlegged partridge)
 other

Method: _____ Year: _____

Glossary:

OECD Guide-line 205
 OECD Guide-line 206
 other

Exposure period a _____ b _____

a: numerical value:
 b: glossary: days; hours

Unit of measurement _____

Glossary:

g/l
 mg/l
 mmol/l
 mol/l
 ug/l
 umol/l

NOEC	terrestrial. org	a.....	b.....	C.....
LC0	terrestrial. org	a.....	b.....	C.....
LC50	terrestrial. org	a.....	b.....	C.....
LC100	terrestrial. org	a.....	b.....	C.....
.....	terrestrial. org	a.....	b.....	C.....

a: glossary: <, <=, =, >, >=, c (circa)
 b: lower value
 c: upper value

Remarks: _____

GLP: _____
 glossary: yes, no, no data

4.7 Biological Effects Monitoring (including biomagnification)

OECD

Remarks: _____

References Nos _____

4.8 Biotransformation and Kinetics in Environmental species

OECD

Remarks _____

References Nos _____

4.9 Other remarks

CEC, OECD

Remarks: _____

References Nos _____

4.7 Biological Effects Monitoring

Describe the results of the studies e.g. on the predominant species in certain ecosystems, monitoring of biological effects and biomagnification (i.e. bioaccumulation through food chains and the environment). Give information on organism, species or ecosystem studied, data on substance analysed (e.g. CAS number and name), analytical method, effects monitored (e.g. thinning of eggshell), monitoring conditions (e.g. water characteristics such as suspended matter, pH, temperature, hardness). Soil/sediment characteristics such as content of organic carbon (%), clay content (%) should be described if available. If data is linked to information in item 3.2, indicate the connection.

Specify the monitoring site and the route of contamination of the site.

4.8 Biotransformation and Kinetics in Environmental species

Describe the results of the studies on absorption, distribution, metabolism and excretion of the chemical in environmental species. Give information on species studied, data on substances including metabolites analysed (e.g. CAS number and name), analytical methods, organs studied, mechanism of the transformation and metabolism, kinetic data on metabolism or absorption and excretion (e.g. half life), data on distribution among organs and effects of the chemicals, if any. Data on concentrations of the parent chemical should be reported in item 3.2. If the data reported here is linked to information in item 3.2, indicate the connection.

4.9 Other Remarks

Give any other relevant information which has not already been described under previous headings of section 4.

5 Toxicity

updated 30 September 1990

5.1 Acute Toxicity

CEC, OECD

5.1.1 Acute oral Toxicity

CEC, OECD

Test substance: _____ References Nos _____

Glossary: as prescribed by 1.1 - 1.8
other _____ purity _____ %
no data _____

Type a _____ Species b _____

a: glossary: LD50, LDLo, LD100, LD0, other
b: glossary: rat, mouse, rabbit, guinea pig,
Syrian hamster, Chinese hamster,
otherMethod: _____ Year: _____
Glossary: OECD Guide-line, 401
Directive 84/449/EEC, B. 1
other (see remarks)

Remarks: _____

Value a _____ b _____ c _____
a: glossary, <, <=, =, >, >=, ca.
b: numerical value
c: Unit of measure
glossary: mg/kgRange of values: a _____ b _____
a: lower value
b: upper value

Remarks: _____

GLP: _____
Glossary: yes, no, no data**5.1 Acute Toxicity**The figures for the LD₅₀ and LC₅₀ should be inserted along with the species in which the estimates were made and references which substantiate the figures. Use one data set for each test.

Range of values: if a range of values is obtained for a test, quote the lower and upper values.

Remarks: where possible give further information (e.g. on test method, test results, dose response curve, other signs of toxicity, validity of the test).

5.1.2 Acute inhalation Toxicity

CEC, OECD

References Nos

Test substance: _____

Glossary: as prescribed by 1.1 - 1.8

other _____ purity _____ %

no data _____

Type a _____ Species b _____

a: glossary: LC50, LC100, LCLo, LC0, other

b: glossary: rat, mouse, rabbit, guinea pig,
Syrian hamster, Chinese hamster,
other

Method: _____ Year: _____

Glossary: OECD Guide-line, 403
Directive 84/449/EEC, B. 2
other (see remarks)

Remarks: _____

Value a _____ b _____ c _____
a: glossary, <, <=, =, >, >=, ca.
b: numerical value
c: Unit of measure
glossary: mg/lExposure time a _____ b _____
a: numerical value
b: glossary: hourRange of values: a _____ b _____
a: lower value
b: upper valueGLP: _____
Glossary: yes, no, no data

Remarks: _____

5.1.3 Acute dermal Toxicity

CEC, OECD

References Nos

Test substance: _____

Glossary: as prescribed by 1.1 - 1.8

other _____ purity _____ %

no data _____

No additional comments

Type a _____ Species b _____

a: glossary: LD50, LD100, LDLo, LD0, other

b: glossary: rat, mouse, rabbit, guinea pig,
Syrian hamster, Chinese hamster,
other

Method: _____ Year: _____
Glossary: OECD Guide-line, 402
Directive 84/449/EEC, B. 3
other (see remarks)

No additional comments

Remarks: _____

Value a _____ b _____ c _____
a: glossary: <, <=, =, >, >=, ca.
b: numerical value
c: Unit of measure
glossary: mg/kg

Range of values: a _____ b _____
a: lower value
b: upper value

Remarks: _____

GLP: _____
Glossary: yes, no, no data

5.1.4 Acute Toxicity (other routes of administration)

Test substance: _____	References Nos
Glossary: as prescribed by 1.1 - 1.8	_____
other _____	_____
no data _____	_____

Type a _____ Species b _____

a: glossary: LD50, LC50, LDLo, LCLo, LD100,
LC100, LC0, LD0, other

b: glossary: rat, mouse, rabbit, guinea pig,
Syrian hamster, Chinese hamster,
other

Route of administration _____

Glossary: i.m. i.p., i.v., s.c., infusion, other,

Method: _____ Year: _____
 Remarks: _____

Value a _____ b _____
 a: glossary: <, <=, =, >, >=, ca.
 b: numerical value

Exposure time: a _____ b _____
 a: numeric value
 b: glossary: hour

Unit of measurement
 glossary: mg/kg, mg/l, other

Range of values: a _____ b _____
 a: lower value
 b: upper value

Remarks: _____

GLP: _____
 Glossary: yes, no, no data

5.2 Corrosiveness and Irritation

5.2.1 Skin Irritation

CEC, OECD

	References Nos
Test substance: _____	_____
Glossary: as prescribed by 1.1 - 1.8	_____
other _____	_____
no data	_____

Species _____
 glossary: rat, mouse, rabbit, guinea pig,
 other, no data

Method: _____ Year: _____
 Glossary: OECD Guide-line, 404
 Directive 84/449/EEC, B. 4
 Draize-Test
 Estimation
 in vitro test
 other (see remarks)

Remarks: _____

5.2 Corrosiveness and Irritation

Describe all available studies for the substance. Fill in one data set for each study. Indicate the result of the test as a classification specified in the glossary. Give any further information necessary to clarify the results. (See ECETOC 1988 Monograph No 11, Eye Irritation and ECETOC 1990 Monograph No 15, Skin Irritation).

5.2.1 Skin Irritation

5.2.2 Eye Irritation

Indicate whether data are available to show that the substance is an irritant or free from irritant properties. Where irritancy has been demonstrated in eyes or on skin this should be indicated. Where data are equivocal this should be indicated by writing ambiguous. References should be given to support these facts.

Classification (see 1.16): _____
 Glossary: highly corrosive (causes severe burns),
 corrosive (causes burns), irritating, not irritating

Remarks: _____

GLP: _____
 Glossary: yes, no, no data

5.2.2 Eye Irritation

CEC, OECD

Test substance: _____ References Nos _____

Glossary: as prescribed by 1.1 - 1.8
 other _____ purity _____ %
 no data _____

Species _____
 Glossary: rat, mouse, rabbit, guinea pig,
 other, no data

Method: _____ Year: _____
 Glossary: OECD Guide-line, 405
 Directive 84/449/EEC, B. 5
 Draize-Test
 other (see remarks)

Remarks: _____

Classification (see 1.16): _____
 Glossary: risk of serious damage to eyes,
 irritating, not irritating

GLP: _____
 Glossary: yes, no, no data

5.3 Sensitization

CEC, OECD

Test substance: _____ References Nos _____

Glossary: as prescribed by 1.1 - 1.8
 other _____ purity _____ %
 no data _____

5.3 Sensitisation

Indicate whether data are available to show that the substance is capable of inducing allergic sensitisation. Where data are equivocal (e.g. substance causes sensitisation in some animals but no evidence of sensitisation in exposed human subjects provide all available references in support. (See ECETOC 1990 Monograph No 14, Skin Sensitisation Testing).

Type a _____ Species b _____

a: glossary: Guinea pig maximization test,
Split adjuvant test,
Freund complete adjuvant test,
Mouse ear swelling test,
Buehler test,
Patch test,
Intracutaneous test,
Mouse local lymphnode assay,
Skin painting test,
Draize test,
Open epicutaneous test,
Mauer optimisation test,
other,
no data

Species: _____
Glossary: rat, mouse, rabbit, guinea pig,
human, other

Method: _____ Year: _____
Glossary: OECD Guide-line, 406
Directive 84/449/EEC, B. 6
other (see remarks)

Remarks: _____

Overall result: _____
Glossary: ambiguous
sensitizing
not sensitizing

Remarks: _____

GLP: _____
Glossary: yes, no, no data

5.4 Repeated Dose Toxicity

CEC, OECD

References Nos

Test substance: _____

Glossary: as prescribed by 1.1 - 1.8
other _____ purity _____ %
no data

5.4 Repeated dose toxicity (subacute)

Exposure period: give the duration of treatment (e.g. 28 days, 90 days)

Interval of application: give the frequency of treatment (e.g. for inhalation studies: 6 hours per day / 7 days per week).

Postexposure observation period: give the duration of the postexposure observation period, if any (e.g. 14 days).

Doses: give the dose level and number of animals for each test group.

Species a _____ Strain b _____
 a: glossary: rat, mouse, rabbit, guinea pig, dog,
 Syrian hamster, Chinese hamster,
 hen, mammal, monkey, other

b: glossary: Sprague-Dawley, Wistar, Fischer 344,
 B6C3F1, CD-1, Strain A, NMRI, C3H,
 Swiss, Himalayan, New Zealand white,
 Beagle, other, no data

Sex a _____ Route of administration b _____
 a: glossary: male, female, male/female, no data
 b: glossary:

feed
 infusion
 gavage
 drinking water
 dermal
 i.m.
 i.p.
 i.v.
 inhalation
 oral
 s.c.
 other

Method: _____ Year: _____

Glossary:

OECD Guide-line, 407
 OECD Guide-line, 408
 OECD Guide-line, 409
 OECD Guide-line, 410
 OECD Guide-line, 411
 OECD Guide-line, 412
 OECD Guide-line, 413
 Directive 84/449/EEC, B. 7
 Directive 84/449/EEC, B. 8
 Directive 84/449/EEC, B. 9
 Directive 87/302/EEC Part B, p 8
 Directive 87/302/EEC Part B, p 12
 Directive 87/302/EEC Part B, p 16
 Directive 87/302/EEC Part B, p 20
 Directive 87/302/EEC Part B, p 27
 other (see remarks)

Remarks: _____

Exposure period _____

Interval of application _____

Postexposure observation period _____

Doses _____

Control group _____

Glossary: yes, no, further information (see
 remarks), no data

NOEL a _____ b _____ c _____

LOEL a _____ b _____ c _____

a: numeric value

b: glossary: mg/kg bw, mg/l

c: glossary: day

Results: _____

Remarks: _____

GLP: _____

Glossary: yes, no, no data

5.5 Genetic toxicity in vitroCEC, OECD
References Nos

Test substance: _____

Glossary: as prescribed by 1.1 - 1.8

other _____ purity _____ %

no data _____

Type:

Bacterial gene mutation assay
 Ames test
 Salmonella typhimurium
 reverse mutation assay,
 Escherichia coli reverse
 mutation assay,
 Mammalian cells gene mutation
 assay
 HGPRT assay
 Mouse lymphoma assay
 Cytogenetic assay
 DNA damage and repair assay
 Sister chromatid exchange
 assay,
 Unscheduled DNA synthesis
 Bacillus subtilis
 recombination assay
 Yeast gene mutation assay
 Gene mutation in
 Saccharomyces cerevisiae,
 Mitotic recombination in
 Saccharomyces cerevisiae
 Yeast cytogenetic assay
 other

5.5 Genetic Toxicity In Vitro

System of testing: specify the test system used e.g. for bacterial gene mutation assays give full identification of bacteria and strains used. Specify cell-lines or cell types.

Remarks: where necessary give further information (e.g. on test method, test results, cytotoxic effects, validity of the test).

Method: _____ Year: _____
 Glossary: _____

OECD Guide-line, 471
 OECD Guide-line, 472
 OECD Guide-line, 473
 OECD Guide-line, 476
 OECD Guide-line, 479
 OECD Guide-line, 480
 OECD Guide-line, 481
 OECD Guide-line, 482
 Directive 84/449/EEC, B. 10
 Directive 84/449/EEC, B. 13
 Directive 84/449/EEC, B. 14
 Directive 87/302/EEC Part B, p 55
 Directive 87/302/EEC Part B, p 58
 Directive 87/302/EEC Part B, p 61
 Directive 87/302/EEC Part B, p 64
 Directive 87/302/EEC Part B, p 68
 Directive 87/302/EEC Part B, p 73
 other (see remarks)

System of testing _____

Metabolic activation _____

Glossary: with, without, with and without,
 no data

Results _____
 Glossary: ambiguous
 negative
 positive

Remarks: _____

GLP: _____
 Glossary: yes, no, no data

5.6 Genetic toxicity in vivo

CEC, OECD

Test substance: _____ References Nos _____

Glossary: as prescribed by 1.1 - 1.8 _____
 other _____
 no data _____ purity _____ %

5.6 Genetic Toxicity In Vivo

Exposure period: give the duration of treatment.

Doses: give the dose level and number of animals for each test group.

Results: state, if possible, whether the overall result is positive, negative or ambiguous. State if the test substance produced statistically-significant, dose-related mutagenic effects. Report experimental observations where relevant including signs of toxicity, time of sacrifice (e.g. for the rodent dominant lethal test).

Remarks: give further information (e.g. on test method, test results, validity of the test, comparisons with in vitro results).

Type: Dominant lethal assay,
 Micronucleus assay,
 Sister chromatid exchange assay,
 Unscheduled DNA synthesis,
 Heritable translocation assay,
 Somatic mutation assay,
 Drosophila SLRL test,
 Mouse spot test,
 Cytogenetic assay,
 Mammalian germ cell cytogenetic
 assay,
 Inhibition of DNA-Synthesis
 other, no data

Species: rat, mouse, rabbit, guinea pig,
 Syrian hamster, Chinese hamster,
 mammal, Drosophila melanogaster,
 other

Strain: Sprague-Dawley, Wistar, Fischer
 344, B6C3F1, CD-1, Strain A,
 NMRI, C3H, Swiss, Himalayan, New
 Zealand white, other, no data

Method: _____ Year: _____

Glossary: OECD Guide-line, 474
 OECD Guide-line, 475
 OECD Guide-line, 477
 OECD Guide-line, 478
 OECD Guide-line, 483
 OECD Guide-line, 484
 OECD Guide-line, 485
 Directive 84/449/EEC, B. 11
 Directive 84/449/EEC, B. 12
 Directive 87/302/EEC Part B, p 71
 Directive 87/302/EEC Part B, p 76
 Directive 87/302/EEC Part B, p 79
 Directive 87/302/EEC Part B, p 82
 Directive 87/302/EEC Part B, p 85
 other (see remarks)

Sex _____
 Glossary: male, female, male/female, no data

Route of administration _____
 Glossary:

feed
 infusion
 gavage
 drinking water
 dermal
 i.m.
 i.p.
 i.v.
 inhalation
 oral
 s.c.
 other

Exposure period: _____

Doses: _____

Results: _____

Remarks: _____

GLP: _____

Glossary: yes, no, no data

5.7 Carcinogenicity

CEC, OECD

Test substance: _____ References Nos _____

Glossary: as prescribed by 1.1 - 1.8
other _____ purity _____ %
no data _____

Species a _____ Strain b _____

a: glossary: rat, mouse, rabbit, guinea pig, dog,
Syrian hamster, Chinese hamster,
mammal, monkey, otherb: glossary: Sprague-Dawley, Wistar, Fischer 344,
B6C3F1, CD-1, Strain A, NMRI, C3H,
Swiss, Himalayan, New Zealand white,
Beagle, other, no dataSex a _____ Route of administration b _____
a: glossary: male, female, male/female, no data
b: glossary:feed
infusion
gavage
drinking water
dermal
i.m.
i.p.
i.v.
inhalative
oral
s.c.
implantation
other

Method: _____ Year: _____

Glossary:

OECD Guide-line, 451
OECD Guide-line, 453
Directive 87/302/EEC Part B, p 32
Directive 87/302/EEC Part B, p 37
other (see remarks)**5.7 Carcinogenicity**

Exposure period: give the duration of treatment (e.g. 2 years).

Interval of Application: give the frequency of treatment (e.g. for
inhalation studies: 6 hours per day/7 days per week).Postexposure observation period: give the duration of the postexposure
observation period, if any (e.g. 14 days).

Doses: give the dose level and number of animals for each test group.

Results: Give a summary of the test results including clinical findings,
haematology, pathology. Report adverse effects in treated groups compared
to control groups. Tumour incidence in treated groups should be compared to
control group incidence. Relate increased incidence of tumour types in
treated groups to dose level, site of effect, sex. Include any other
relevant information on carcinogenic action e.g. pre-neoplasia,
hyperplasia. Indicate other data which may influence tumour formation e.g.
bodyweight changes, haematology. Ensure that tumour types and their sites
are clearly identified. Make an overall assessment of carcinogenic
potential. When the result is inconclusive, state the reasons.Remarks: where necessary give additional information on the test method,
results etc. Refer to any information on mechanisms of action and
metabolic or pharmacokinetic data relevant to carcinogenic activity. (See
ECETOC 1986), Technical Report No 21, 'A Guide to Classification of
Carcinogens, Mutagens and Teratogens under the VI Amendment).

Remarks: _____

Exposure period _____

Interval of application _____

Postexposure observation period _____

Doses _____

Control group _____

Glossary: yes, no, further information (see remarks), no data

Results: _____

Remarks: _____

GLP: _____
Glossary: yes, no, no data

5.8 Toxicity to Reproduction

CEC, OECD

References Nos

Test substance: _____

Glossary: as prescribed by 1.1 - 1.8
other _____ purity _____ %
no data _____

Method: _____ Year: _____

Glossary:
OECD Guide-line, 415
OECD Guide-line, 416
Directive 87/302/EEC Part B, p 43
Directive 87/302/EEC Part B, p 47
other (see remarks)

Type: _____
Glossary: Fertility,
One generation study,
Two generation study,
other

5.8 Toxicity to Reproduction

Premating exposure period: give the duration of the dosing period prior to the mating period for males and females and if possible the age of the animals at the start of dosing (e.g. ten weeks dosing for male rats starting at 6 weeks old).

Duration of the test: give the total duration of the test including the premating exposure period.

Doses: give the dose level and the number of animals in each test group. Give the frequency of treatment (e.g. for inhalation studies: 6 hours per day / 7 days per week).

NOEL Parental: if possible give the no observable effect level for parental males and females.

NOEL F1 Offspring: if possible give the no observable effect exposure level for F1-generation animals.

NOEL F2 Offspring: if possible give the no observable effect exposure level for F2 generation animals.

Test results: give a summary of test results. Include clinical data (e.g. body weight, food consumption, clinical examination, examination of litters and litter size) and post-mortem examination (e.g. gross pathology, histopathology). Report relationships between the dose of the test substance and the incidence and severity of abnormalities, body weight changes, effects on mortality, fertility index (pregnancies/mating), abortions, corpora lutea, pup weights, other survival indices (e.g. live birth index) and other toxic effects. Note where abnormalities occur at treatment levels lower than those toxic to the mothers. (See ECETOC 1986, Technical Report No 21 'A Guide to the Classification of Carcinogens, Mutagens and Teratogens under the VI Amendment').

Species a _____ Strain b _____
 a: glossary: rat, mouse, rabbit, guinea pig,
 Syrian hamster, Chinese hamster,
 other
 b: glossary: Sprague-Dawley, Wistar, Fischer 344,
 B6C3F1, CD-1, Strain A, NMRI, C3H,
 Swiss, Himalayan, New Zealand white,
 other, no data

Sex a _____ Route of administration b _____

a: glossary: male, female, male/female, no data

b: glossary:

feed	infusion
gavage	drinking water
dermal	i.m.
i.p.	i.v.
inhalation	oral
s.c.	other

Premating exposure period: male _____
 female _____

Duration of the test: _____

Doses: _____

Control group _____
 Glossary: yes, no, further information (see
 remarks), no data

Remarks: _____

NOEL Parental: a _____ b _____ c _____
 NOEL F1 Offspring: a _____ b _____ c _____
 NOEL F2 Offspring: a _____ b _____ c _____
 a: numeric value
 b: glossary: mg/kg bw/day, mg/l/day
 c: other

Test results: _____

GLP: _____
 Glossary: yes, no, no data

5.9 Developmental Toxicity /Teratogenicity

Test substance: _____	References Nos
Glossary: as prescribed by 1.1 - 1.8	_____
other _____	purity _____ %
Method: _____	Year: _____
Glossary	
OECD Guide-line, 414	
Directive 87/302/EEC Part B, Page 24	
other (see remarks)	
Remarks: _____	

Species a _____	Strain b _____
a: glossary: rat, mouse, rabbit, guinea pig,	
Syrian hamster, Chinese hamster,	
other _____	
b: glossary: Sprague-Dawley, Wistar, Fischer 344,	
B6C3F1, CD-1, Strain A, NMRI, C3H,	
Swiss, Himalayan, New Zealand white,	
other, no data	
Route of administration _____	
Glossary:	
feed	infusion
gavage	drinking water
dermal	i.m.
i.p.	i.v.
inhalation	oral
s.c.	no data
other	
Duration of test _____	
Exposure period _____	
Interval of application _____	
Doses _____	
Control group : _____	
Glossary: yes, no, no data, further information	
(see remarks), no data	
Remarks: _____	

5.9 Developmental Toxicity/Teratogenicity

Duration of the test - Give the day of gestation (with day 0 being defined as the day on which a vaginal plug and/or sperm was observed) on which the dams were sacrificed or, for certain developmental studies, the age of the pups when killed.

Exposure period: give the period of gestation over which dams were exposed to the test compound (e.g. days 6-15 where day 0 is the day on which vaginal plug and/or sperm are observed).

Interval of application: give the frequency of treatment (e.g. for inhalation studies: 6 hours per day/7days per week).

Doses: give the dose level and the number of animals in each test group (if appropriate indicate any treatment of male animals).

NOEL Maternal Toxicity: if possible give the no observable effect exposure level for maternal animals.

NOEL Teratogenicity: if possible give the no observable effect exposure level for teratogenic effects.

Test results: give a summary of test results. Include clinical data (e.g. body weight, food consumption, clinical signs and mortality) and post-mortem examination of reproductive organs (e.g. gross pathology, number of corpora lutea, embryonic or fetal death, morphological examination of fetuses). Give information about fetal data (e.g. live/dead soft tissue and skeletal defects),. Indicate the type of abnormalities observed (e.g. cleft palate, fused ribs, hydrocephalus etc.). Note where abnormalities occur at treatment levels lower than those toxic to the mothers. (See ECETOC 1989, Technical Report No 21, 'A Guide to the Classification of Carcinogens, Mutagens and Teratogens under the VI Amendment').

Value glossary other
 NOEL Maternal Toxicity: a _____ b _____ c _____
 NOEL Teratogenicity: a _____ b _____ c _____
 a: numeric value
 b: glossary: mg/kg bw/day, mg/l/day
 c: other

Test results: _____

Remarks: _____

GLP: _____
 Glossary: yes, no, no data

5.10 Other relevant information CEC, OECD (e.g. Toxicodynamics, Immunotoxicity, Neurotoxicity etc)

Remarks: _____

5.11 Experience with Human Exposure CEC, OECD (including Biological Monitoring) Give full Description of Study Design, Effects of Accidental or Occupational Exposure, Epidemiology.

References Nos _____

6 List of References

a _____ b _____
 c _____ d _____ e _____ f _____

a: reference No
 b: auther(s)
 c: name of scientific journal, book, etc
 d: year of publication
 e: volume
 f: page

5.10 Other Relevant Information

Remarks: provide references to information on other toxic effects produced by the substance in animals or man. Give short description of study design and observed effects including the NOEL. Indicate any differences or similarities between animal species and man.

5.11 Experience with Human Exposure

Provide references to experimental studies on man and clinical and epidemiological studies on the substance. In a summary comment, giving reference where possible, on the strengths and weaknesses of the studies. Note whether exposure was to the substance alone; where not, the other substances should be noted.